UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE ASACOL ANTITRUST LITIGATION	)	**Civil Action No. 15-cv-12730-DJC**

MEMORANDUM AND ORDER

CASPER, J. **November 9, 2017**

I. Introduction

This is a putative class action in which the Plaintiffs, members of a putative class of end-payor purchasers of certain pharmaceutical products,[1] allege that the Defendants, manufacturers of certain pharmaceutical products, engaged in exclusionary conduct impermissible under antitrust laws by pulling one product, Asacol 400mg, from the market at the same that it introduced a new product, Delzicol. For the reasons set forth below, the Court DENIES the parties' motions to exclude testimony, D. 426; D. 427; D. 428; D. 429; D. 430; D. 431; D. 444, provides the reasons for ALLOWING the Plaintiffs' motion for class certification under Fed. R. Civ. P. 23(b)(3), D. 380, as it ruled in D. 559, and DENIES the Defendants' motion for summary judgment, D. 445.

II. Factual Background

The following facts are taken from the parties' statements of material facts, D. 450; D. 509; D. 510; D. 545, and accompanying exhibits unless otherwise noted.

[1] This case also involves a separate plaintiff class of direct purchasers. The approval of the proposed settlement of the claims of that class awaits a final fairness hearing. D. 461.

A. Regulatory Background

Prior to approving a product, the Food and Drug Administration ("FDA") reviews a New Drug Application ("NDA") to determine whether a proposed drug is safe and effective for its proposed uses. 21 U.S.C. § 355; D. 450 ¶ 195; D. 510 ¶ 195. Even after the FDA approves an NDA, the agency continues to monitor the safety of the drug and retains the authority to withdraw its approval if it finds that the drug is not safe or effective. 21 U.S.C. § 355(e); D. 450 ¶¶ 199-200; D. 510 ¶¶ 199-200.

After an NDA has been approved, applicants who wish to manufacture a generic version of the approved drug may receive permission to do so by submitting an Abbreviated New Drug Application ("ANDA"). D. 450 ¶ 31; D. 510 ¶ 31. The FDA then determines whether the drug proposed in the ANDA is sufficiently "bioequivalent" to the drug that was already approved – termed the "reference listed drug." D. 450 ¶ 31; D. 510 ¶ 31; D. 458-5 at 455. When a generic manufacturer submits an ANDA, it makes a filing to the FDA regarding the status of patents associated with the NDA of the reference listed drug. D. 450 ¶ 35; D. 510 ¶ 35. In that filing, the generic manufacturer must certify: (1) that the manufacturer of the reference-listed drug did not indicate to the FDA that there were any patents associated with the NDA of the reference listed drug; (2) that the patents associated with the NDA of the reference listed drug have expired; (3) that the patents associated with the NDA of the reference listed drug will expire before the generic manufacturer will begin marketing its product; or (4) that the patents associated with the NDA of the reference listed drug are invalid, unenforceable, or will not be infringed by the generic manufacturer. 21 U.S.C. § 355(j)(2)(A)(vii); D. 450 ¶ 35; D. 510 ¶ 35. A generic manufacturer certifying that it will not market the drug until the relevant patents expire is called a "Paragraph III certification," and certifying that the patents associated with the NDA are invalid,

unenforceable, or will not be infringed by the generic manufacturer is called a "Paragraph IV certification." D. 450 ¶ 35; D. 510 ¶ 35.

Under certain circumstances, the first generic manufacturer who submits an ANDA with a Paragraph IV certification will be eligible for 180 days of market exclusivity, during which it is the only manufacturer authorized to market a generic version of the reference listed drug. D. 450 ¶ 38; D. 510 ¶ 38. Generic products typically gain market share from brand-name products by virtue of state laws that allow or require pharmacists to substitute a generic product for the reference listed drug that is sufficiently bioequivalent. D. 509 ¶¶ 60-62; D. 545 ¶¶ 60-62.

The filer of an ANDA with a Paragraph IV certification must provide notice to the holder of the NDA of the reference listed drug, who may then choose to file suit in federal court asserting its patent rights against the ANDA filer. D. 450 ¶ 39. However, the filer of an ANDA with a Paragraph III certification need not provide the same notice. 21 U.S.C. § 355(b)(3)(A). The filing of an ANDA with a Paragraph III certification need not be public. D. 509 ¶ 279; D. 545 ¶ 279. The FDA does, however, publicly announce its tentative or final approval of an ANDA. D. 450 ¶ 41; D. 510 ¶ 41.

B. The FDA Approves Asacol and Asacol HD for Ulcerative Colitis

"Ulcerative colitis is a chronic inflammatory bowel disorder that typically causes bloody diarrhea, rectal urgency, tenesmus, and abdominal cramping." D. 450 ¶ 1; D. 510 ¶ 1. The condition is cyclical, such that patients will experience periods of time without symptoms intermixed with periods of time with symptoms, termed "flares." D. 450 ¶ 2; D. 510 ¶ 2. Due to the cyclical nature of the condition, patients may use one mode of treatment during flares and another mode of treatment continuously, even when the patient is not experiencing symptoms. D. 450 ¶ 3; D. 510 ¶ 3. The most common treatment for ulcerative colitis is a class of drugs containing

the active ingredient mesalamine. D. 450 ¶ 4; D. 510 ¶ 4. Mesalamine, however, is ineffective at providing relief if it is released either too early or too late. D. 450 ¶ 6; D. 510 ¶ 6.

Proctor and Gamble Pharmaceuticals Inc. ("P&G") submitted an NDA to the FDA, requesting permission to sell a delayed-release oral tablet containing 400mg of mesalamine, sold under the brand name "Asacol" ("Asacol 400mg"). D. 450 ¶ 7; D. 510 ¶ 7. There were two patents associated with Asacol 400mg, both of which expired on July 30, 2013. D. 450 ¶ 11; D. 510 ¶ 11. The Asacol 400mg tablet contained an acrylic based delayed-release coating, such that the active ingredient is released in the colon. D. 450 ¶ 9; D. 510 ¶ 9. This coating contained a plasticizer known as dibutyl phthalate ("DBP"). D. 450 ¶ 47; D. 510 ¶ 47. The FDA approved this NDA on January 31, 1992. D. 450 ¶ 7; D. 510 ¶ 7.

On May 29, 2008, the FDA approved a new NDA from P&G – this one for a 800mg, long-acting mesalamine tablet, to be sold under the brand name "Asacol HD." D. 450 ¶ 12; D. 510 ¶ 12. Asacol HD differs from Asacol 400mg in two important ways: first, it is 800mg, instead of 400mg, D. 450 ¶ 13; D. 510 ¶ 13; and second, it has a dual-layer coating rather than a single-layer coating. D. 450 ¶ 14; D. 510 ¶ 14. The coating for Asacol HD when launched contained DBP, like the coating for Asacol 400mg. D. 450 ¶ 47; D. 510 ¶ 47. Asacol HD was launched on July 7, 2009. D. 450 ¶ 18; D. 510 ¶ 18. The patents associated with Asacol HD are due to expire on November 15, 2021. D. 509 ¶ 24; D. 545 ¶ 24.

C. P&G and the FDA Discuss Removing DBP from Asacol and Asacol HD

In March 2009, after the approval of Asacol HD but before its sale, the FDA held a teleconference with P&G regarding whether "P&G would consider removing DBP from Asacol 400mg." D. 450 ¶ 21; D. 510 ¶ 21; D. 456-6 at 58-59. According to P&G, the FDA requested the teleconference with P&G because it was aware of the "potential health risks associated with exposure to DBP demonstrated in numerous studies" and wanted to "discuss the issue" with P&G.

D. 456-6 at 58. It the teleconference, P&G indicated that it was having internal discussions about removing DBP. D. 456-6 at 59. The FDA asked about P&G's plan to remove DBP from the Asacol 400mg formulation, stating that the FDA felt "some urgency on this as the public is interested in removing this chemical from products," and indicated that the FDA was "suggesting DBPs should be replaced." D. 456-6 at 59. The FDA indicated that its timetable on having a dialogue with P&G about DBP was "as fast as possible." D. 456-6 at 60.

On April 16, 2009, P&G sent a proposed plan to reformulate Asacol 400mg without DBP to the FDA. D. 450 ¶ 85; D. 510 ¶ 85. The proposed plan suggested that the FDA allow P&G to prove bioequivalence between the then-current version of Asacol 400mg and a reformulated version of Asacol 400mg without DBP through "in vitro dissolution testing." D. 450 ¶ 86; D. 510 ¶ 86.

The parties dispute the extent to which there actually was a concern at P&G regarding the premature release of mesalamine in the Asacol products caused by premature dissolution that might have informed P&G's aims in reformulating the Asacol products. Several years prior, in 2005, Asacol HD had been recalled in Canada due to dissolution testing problems, and as a result, P&G had developed "Quick Test" methods to identify batches of product with microfractures, which made the product susceptible to dissolution problems. D. 450 ¶¶ 73-74; D. 510 ¶¶ 73-74. At some point in 2009, P&G outlined the use of "soft handling" – avoiding putting physical stress on the tablets across the supply chain by, for example, minimizing drops – as a strategy. D. 450 ¶ 77; D. 510 ¶ 77; D. 456-2 at 4. In light of this strategy, it's not clear that P&G considered the problem of dissolution failures to be ongoing rather than solved by the soft handling approach. D. 456-2 at 4, 54.

On April 23, 2009, the FDA held a meeting with P&G regarding Asacol HD. D. 450 ¶ 66; D. 510 ¶ 66; D. 456-3 at 4. According to P&G, it proposed to the FDA a change to the specifications for the dissolution rate (i.e., the rate set by the FDA for the percentage of tablets that opened at a particular pH) and the FDA was supportive of that change. D. 450 ¶ 72; D. 510 ¶ 72; D. 456-3 at 4. The specification for Asacol HD at that time required a dissolution rate of 1% at a pH of 6, and P&G was proposing to change the specification for the dissolution rate to 4%. D. 450 ¶ 72; D. 510 ¶ 72; D. 456-3 at 4. P&G requested this change to allow for "one tablet in the sample [to] fail," that is, prematurely release the active ingredient, "without failing the specification," even though P&G "[did] not have a history of failing the 1% spec on release testing." D. 456-8 at 9. According to P&G, the FDA also expressed that reformulation of Asacol HD to remove DBP "needs to proceed with urgency." D. 450 ¶ 66; D. 510 ¶ 66; D. 456-3 at 4. The FDA also stated that it wanted the reformulation of Asacol HD to remove DBP to "solve the current dissolution issue." D. 450 ¶ 72; D. 510 ¶ 72; D. 456-3 at 4.

There were further communications between the FDA and P&G on these matters. D. 450 ¶ 88; D. 510 ¶ 88; D. 456-2 at 81-83. By August 6, 2009, the FDA sent a letter to P&G rejecting P&G's proposed use of "in vitro dissolution testing" and instead requiring P&G to perform "in vitro methods (comparative dissolution)" to show bioequivalence between the then-currently marketed version of Asacol 400mg and the reformulated version of Asacol 400mg. D. 450 ¶ 89; D. 510 ¶ 89; D. 456-6 at 88. On August 24, 2009, the FDA conferred with P&G to discuss bioequivalence testing and indicated that it might consider an approach of "combined in vitro dissolution and PK study," but also stated that it was in "heavy discussion internally in regard to Division policy on reformulation changes." D. 450 ¶¶ 94-98; D. 510 ¶¶ 94-98; D. 456-6 at 93.

On October 12, 2009, P&G again discussed the subject of bioequivalence testing with the FDA and stated that Warner Chilcott (which by that point had agreed to purchase P&G's Asacol business) was "leaning towards clinical trials because [it] was 'concerned about the impact on the global business as well as lowering the bar for generics.'" D. 450 ¶ 99; D. 510 ¶ 99.

An October 20, 2009 Technical Report indicated that P&G tested two compounds, dibutyl sebacate ("DBS") and triethyl citrate ("TEC") as potential replacements for Asacol 400mg and Asacol HD. D. 450 ¶ 87; D. 510 ¶ 87; D. 456-8 at 16. The Technical Report concluded that DBS was the "best match to the current DBP containing formulation." D. 456-8 at 16.

D. Warner Chilcott Purchases the Asacol Products

On October 30, 2009, Warner Chilcott purchased P&G's portfolio of pharmaceutical products, including Asacol 400mg and Asacol HD. D. 450 ¶¶ 19-20; D. 510 ¶¶ 19-20. Warner Chilcott was concerned about the impending expiration of the patent for Asacol 400mg, but appeared to believe that it could manage that risk through product improvement including the recent launch of Asacol HD. D. 509 ¶¶ 148-155; D. 545 ¶¶ 148-155. The efforts of P&G and Warner Chilcott to convert patients from Asacol 400mg, which would lose patent protection in 2013, to Asacol HD, which would not lose patent protection until 2021, met with only limited success. D. 509 ¶¶ 156-159; D. 545 ¶¶ 156-159. By 2011, only approximately 22% of Asacol 400mg prescriptions transitioned to Asacol HD, which was far short of Warner Chilcott's internal projections. D. 509 ¶ 167; D. 545 ¶ 167.

At the time of the purchase, Warner Chilcott was also aware of P&G's discussions with the FDA about the reformulation of Asacol 400mg and Asacol HD to replace DBP. D. 450 ¶ 22; D. 510 ¶ 22. There is a dispute between the parties over whether P&G conveyed any specific concerns it may have had regarding the performance of the DBP-containing coating of Asacol 400mg and Asacol HD to Warner Chilcott. Compare D. 450 ¶¶ 24-26 with D. 510 ¶¶ 24-26.

E. Warner Chilcott Negotiates Bioequivalence Testing with the FDA

Warner Chilcott proceeded with the discussions P&G had been having with the FDA over the bioequivalence testing for the reformulation of Asacol 400mg to remove DBP. By November 24, 2009, Warner Chilcott had submitted a draft protocol for a clinical end point study to establish bioequivalence to the FDA. D. 450 ¶ 101; D. 510 ¶ 101. On January 21, 2010, the FDA responded to Warner Chilcott's draft protocol with an Advice Letter. D. 450 ¶ 106; D. 510 ¶ 106. On February 22, 2010, Warner Chilcott filed a citizen petition with the FDA requesting that the "requirements for establishing bioequivalence for any reference listed delayed-release mesalamine tablet include: a clinical efficacy endpoint study; comparative [PK] testing under fed and fasted conditions; and rigorous in vitro dissolution testing," and that the FDA promulgate official guidance to that effect. D. 450 ¶¶ 108-09; D. 510 ¶¶ 108-09. On April 22, 2010, the FDA communicated that "it will be acceptable to establish bioequivalence through special dissolution and PK studies," but that "if PK and dissolution testing results are not convincing, then a clinical trial may be necessary to establish equivalence based on clinical end points." D. 450 ¶¶ 113-14; D. 510 ¶¶ 113-14.

The FDA's May 20, 2010 response to Warner Chilcott's citizen petition stated that the "FDA continues to recommend in vitro dissolution testing but now recommends comparative PK studies rather than comparative clinical endpoint studies to show bioequivalence for these products." D. 456 at 3. It acknowledged that this presented a departure from its 2007 position that "comparative clinical endpoint studies, rather than PK studies, should be used (along with in vitro dissolution studies) to show bioequivalence in orally administered extended or delayed release mesalamine drugs." D. 456 at 8. It attributed the change to "new data from PK and comparative clinical endpoint studies in modified release mesalamine products as well as recent developments

in regulatory science concerning analysis of PK data." D. 456 at 9. The FDA denied the request to publish guidance regarding bioequivalence testing. D. 450 ¶ 130; D. 510 ¶ 130.

F. Warner Chilcott Shifts to a Capsule Formulation of Mesalamine (Delzicol)

Contemporaneous with discussions with the FDA on bioequivalence testing, Warner Chilcott began to consider a potential "new product" that would be different from Asacol 400mg in more ways than just removing DBP. D. 509 ¶ 114; D. 513-46 at 2-3; D. 545 ¶ 114. By October 2010, Warner Chilcott was pursuing a "capsule containing 400mg of mesalamine," "compressed into four 100-mg mini-tablets encapsulated into a standard gelatin capsule." D. 450 ¶ 131; D. 510 ¶ 131.

On November 2, 2010 Warner Chilcott conferred again with the FDA about bioequivalence testing for the reformulation of Asacol 400mg. D. 450 ¶ 132; D. 510 ¶ 132; D. 456-7 at 12. In addition to discussing specific testing protocols, Warner Chilcott also informed the FDA that it was "considering possible reformulation of Asacol 400-mg tablets to . . . a capsule formulation." D. 450 ¶ 133; D. 510 ¶ 133.

In early 2011, Warner Chilcott worked on the proposed capsule formulation for testing, with the goal of having a batch prepared by July 1, 2011. D. 450 ¶ 138; D. 510 ¶ 138. By June 2011, management had confirmed that the prior "DBP replacement project" was "on-hold" because the plan was now "to focus on the Asacol LCM [life-cycle management] projects" including the capsule project. D. 509 ¶ 118; D. 513-45 at 2; D. 545 ¶ 118. By mid-June 2011, it was determined that the capsules had higher water levels than expected, which could jeopardize the July 1, 2011 production date. D. 450 ¶ 139; D. 510 ¶ 139; D. 456-11 at 8. By August 2011, Warner Chilcott planned to proceed with one 400-mg DBS tablet in a capsule instead of four 100-mg tablets." D. 450 ¶ 140; D. 510 ¶ 140. By August 2011, Warner Chilcott appeared to be concerned that "Asacol 400 capsule[s] would not be bioequivalent to current Asacol 400 have

shifted focus to new format" such that Warner Chilcott's product could "be a moving target for generics to delay their entry" and "gain time to further modify the coating for true patent protection." D. 509 ¶ 188; D. 514-34; D. 545 ¶ 188.

On October 21, 2011, Warner Chilcott submitted an amended protocol to the FDA, which stated, among other things, that Warner Chilcott was going to submit a capsule formulation, with a single 400-mg tablet, and without DBP, for bioequivalence testing. D. 450 ¶ 143; D. 510 ¶ 143. In that same document, Warner Chilcott stated that the tablet was encapsulated in a "hydroxypropyl methylcellulose (HPMC) capsule to provide a protective layer to maintain the integrity of the delayed-release coating under the mechanical stresses of handling and packaging. This capsule layer will dissolve earlier in the gastrointestinal (GI) tract and will not interfere with the delayed release mechanism." D. 450 ¶ 144; D. 510 ¶ 144; D. 456-9 at 6. Between that point and March 2, 2012, the FDA and Warner Chilcott communicated regarding the specifications of the bioequivalence testing that would necessary. D. 450 ¶¶ 145-150; D. 510 ¶¶ 145-150. Ultimately, on June 13, 2012, the FDA agreed that Warner Chilcott had satisfactorily shown bioequivalence. D. 450 ¶ 157; D. 510 ¶ 157.

Notwithstanding a delay in obtaining validated experimental data to support Warner Chilcott's hypothesis regarding the relative stability of the capsule, D. 509 ¶¶ 199-213; D. 545 ¶¶ 199-213, on July 30, 2012, Warner Chilcott submitted an NDA to the FDA for the 400mg mesalamine delayed release single tablet in a capsule, without DBP, which was later sold under the name Delzicol. D. 450 ¶¶ 51-52; D. 510 ¶¶ 51-52. Warner Chilcott requested an expedited "6 month priority review" from the FDA on the NDA for Delzicol on the grounds that the FDA had expressed a safety concern with DBP, which was granted. D. 450 ¶ 53; D. 510 ¶ 53. On February 1, 2013, the FDA approved the NDA for Delzicol. D. 450 ¶ 54; D. 510 ¶ 54. In approving the

label for Delzicol, the FDA recommended a removal of certain warning language regarding DBP. D. 450 ¶¶ 173-176; D. 510 ¶¶ 173-176.

G. Warner Chilcott Launches Delzicol, Pulls Asacol, and Shifts to a Patented Capsule for Delzicol

On March 18, 2013, Warner Chilcott launched Delzicol. D. 450 ¶ 55; D. 510 ¶ 55. On the same date that Warner Chilcott launched Delzicol, Warner Chilcott stopped selling and marketing Asacol 400mg. D. 450 ¶ 57; D. 510 ¶ 57. The "hard switch" – that is, pulling Asacol 400mg from the market once Delzicol was launched – meant that patients who had been taking Asacol 400mg no longer had the option of continuing with that product – they had to choose between switching to Delzicol, switching to Asacol HD (which was still on the market but had a different dosage), or switching to a different product. D. 509 ¶ 79; D. 545 ¶ 79.

In an earnings call in February 2013, Roger Boissonneault, the chief executive of Warner Chilcott, explained that the result of pulling Asacol 400mg from the market at the same time as the Delzicol launch would be that "the generic company doesn't even get launched because the reference product will be Delzicol." D. 509 ¶ 71; D. 545 ¶ 71. "There won't be any Asacol out there. We've seen that happen with Doryx [another Warner Chilcott product], when the generic company got the product approved and, by that time, the product had moved on." D. 509 ¶ 71; D. 545 ¶ 71.

When Warner Chilcott pulled Asacol 400mg from the market, sales of Asacol 400mg and of the Asacol-branded products as a whole declined. D. 509 ¶¶ 331-32; D. 545 ¶¶ 331-32. There is a dispute between the parties regarding whether the sales of oral mesalamine drugs generally declined. D. 509 ¶ 333; D. 545 ¶ 333.

When Delzicol first launched, the capsule on the tablet was an unpatented design. 450 ¶ 178; D. 510 ¶ 178. On March 12, 2013, Warner Chilcott submitted a supplemental NDA to the

FDA requesting permission to use a patented capsule, termed the "Qualicaps capsule" for Delzicol. There is a dispute between the parties regarding whether Warner Chilcott experienced any cost savings as a result of the switch to the Qualicaps capsule. D. 450 ¶ 182; D. 510 ¶ 182. The FDA approved the NDA for the Qualicaps capsule on July 9, 2013. D. 450 ¶ 180; D. 510 ¶ 180. Warner Chilcott represented to the FDA that it had begun manufacturing Delzicol with the Qualicaps capsule in August 2013, but as of March 7, 2014, it had not yet begun selling Delzicol with the Qualicaps capsule. D. 450 ¶ 181; D. 510 ¶ 181.

By 2015, Warner Chilcott introduced a 4x100mg formulation for Delzicol which was approved for pediatric use, and allows patients to open the capsule to swallow the 100mg tablets, allowing for flexible dosing. D. 450 ¶¶ 331-34; D. 510 ¶¶ 331-34.

H. Subsequent Conduct by the Defendants

Unlike for Asacol 400mg, Warner Chilcott's removal of DBP from the Asacol HD formulation was not accompanied by other changes. Warner Chilcott filed a supplementary NDA to the FDA regarding the new, DBP-free formulation of Asacol HD on September 24, 2015. D. 509 ¶ 125; D. 545 ¶ 125. The reformulation of Asacol HD did not go through expedited review. D. 509 ¶ 125; D. 545 ¶ 125. Asacol HD contained no less DBP than Asacol 400mg; in fact, it contained twice as much DBP per tablet. D. 509 ¶ 125; D. 545 ¶ 125. The FDA approved the supplementary NDA on May 5, 2016. D. 509 ¶ 125; D. 545 ¶ 125. In the United Kingdom, Allergan, Warner Chilcott's successor, launched a version of Asacol 400mg without DBP but also without a capsule. D. 509 ¶ 228; D. 545 ¶ 228.

On October 1, 2013, Actavis PLC, which is now known as Allergan PLC, acquired Warner Chilcott, including the Asacol line of products. D. 509 ¶ 9; D. 545 ¶ 9.

I. FDA Policy Regarding DBP Generally

The FDA maintained a policy of encouraging manufacturers to discontinue the use of DBP and to require clearer warnings regarding the risks of DBP, but did not prohibit the use of DBP. In 2009, the FDA requested a revision to the label of Asacol 400mg and Asacol HD to provide information on the "effects of DBP in animals and humans." D. 450 ¶ 111; D. 510 ¶ 111. Warner Chilcott released an updated label containing that information in May 2010. D. 450 ¶ 112; D. 510 ¶ 112. In March 2012, the FDA issued Draft Guidance in which it outlined its "current thinking on the potential human health risks associated with exposure to . . . DBP." D. 456-3 at 109. In December 2012, the FDA released Final Guidance on the subject. D. 450 ¶ 50; D. 510 ¶ 50. Like the Draft Guidance, the Final Guidance communicated the FDA's thinking on the health risks associated with exposure to DBP and clarified that it merely provided recommendations rather than directives. D. 456-11 at 178. The Division of Gastroenterology and Inborn Errors Products recommended that "it was prudent to change the professional labeling of Asacol [400mg] to provide information on the effects of DBP in animals and humans, as well as requiring the sponsor to reformulate their product without DBP." D. 450 ¶ 67; D. 510 ¶ 67; D. 456-6 at 64. The FDA did not at any point pull Asacol HD from the market despite the fact that Asacol HD continued to have a DBP-containing coating until May 5, 2016. D. 509 ¶ 125; D. 545 ¶ 125.

J. Generic Entry

The parties dispute whether generic entry for Asacol 400mg would have occurred but for Warner Chilcott's decision to pull it from the market. The following facts relevant to that determination, however, are undisputed.

First, Warner Chilcott was concerned about generic competition for Asacol 400mg. D. 509 ¶ 248; D. 515-10 at 2; D. 513-17 at 2; D. 509 ¶ 241; D. 545 ¶ 241; D. 514-39 at 6.

Second, Warner Chilcott had an agreement with Lupin Pharmaceuticals, Inc. ("Lupin"), a generic manufacturer, to be an "authorized generic" – that is, Lupin would distribute Asacol 400mg supplied by Warner Chilcott as a generic product. D. 509 ¶ 266; D. 545 ¶ 266; D. 456-12 at 3. Under the terms of that agreement, Lupin was authorized to sell generic Asacol 400mg supplied by Warner Chilcott as soon as it was able, but only after another generic manufacturer had already entered the market for Asacol. D. 456-12 at 9. Lupin was to submit its first purchase order for generic Asacol 400mg from Warner Chilcott within 30 days of another manufacturer selling a generic version of Asacol 400mg. D. 456-12 at 10.

Third, there is limited information regarding which, if any, generic manufacturers had filed ANDAs with a Paragraph III certification for Asacol 400mg. The FDA never filed any notice of either tentative or final approval of an ANDA for a generic version of Asacol 400mg. D. 450 ¶ 211; D. 510 ¶ 211. The parties agree that neither Lupin nor another manufacturer, Zydus Pharmaceutical (USA) Inc. ("Zydus"), filed an ANDA for Asacol. Lupin believed that nine manufacturers had filed Drug Master Files ("DMFs"), a filing regarding manufacturing processes for a product that might be used to support an ANDA filing. D. 509 ¶¶ 274-275; D. 545 ¶¶ 274-275; D. 515-14 at 3. There is no evidence about whether any of the following generic manufacturers had filed ANDAs with a Paragraph III certification for Asacol 400mg: Actavis Pharma. ("Actavis"), Mylan Pharmaceuticals, Inc. ("Mylan"), Teva Pharmaceutical Industries Ltd. ("Teva"), Watson Pharmaceuticals ("Watson"); Pendopharm, Sanis Health, Aspen Pharmacare, Dr. Falk GmBH, Merckle GmBH, Tillotts Pharma, Sandoz (Novartis), Aurobindo Pharmaceuticals, Torrent Laboratory Inc., West Coast, Zota Healthcare Ltd., Ipca Laboratories, Bracco, Chiesi, Crinos, Dorm, SOFAR, Wellpharma. D. 450 ¶¶ 206, 267; D. 510 ¶¶ 206, 267. Roxane Laboratories, Inc. ("Roxane") and Par Pharmaceutical, Inc. ("Par") had filed ANDAs with

a Paragraph IV certification – certifying that their products did not infringe the patents associated with Asacol 400mg – but neither manufacturer proved bioequivalence to the FDA and those ANDAs were withdrawn. D. 509 ¶¶ 304-314; D. 545 ¶¶ 304-314.

Fourth, it is not clear how long the FDA would have taken to approve an ANDA for generic Asacol 400mg once any ANDA was submitted. According to the FDA, its "median review time from ANDA receipt to approval" was 27.85 months in 2010 and 29.52 months in 2011, but the time for individual drugs might be significantly above or below that median. D. 450 ¶¶ 212-215; D. 510 ¶¶ 212-215. The FDA could have expedited review of the first ANDA for generic Asacol 400mg, as FDA policy allows expedited review of "first generic products for which there are no blocking patents or exclusivities on the reference listed drug." D. 509 ¶¶ 316-17; D. 545 ¶¶ 316-17

Fifth, generic manufacturers had significant economic incentives to produce a generic version of Asacol 400mg if Warner Chilcott did not pull Asacol 400mg from the market and there is a dispute regarding whether they had the technical capacity to do so. D. 509 ¶¶ 284-85, 295-297; D. 545 ¶¶ 284-85, 295-297; D. 426-5 at 20. Generic manufacturers had already produced internationally delayed-release mesalamine oral tablets with a Eudragit S coating, similar to the Asacol 400mg tablet. D. 509 ¶ 296; D. 545 ¶ 296. Additionally, the FDA's decision to focus on PK testing rather than on clinical studies was considered by the Defendants to be "lowering the bar" to generic entry. D. 509 ¶ 289; D. 545 ¶ 289. The FDA had already approved two other oral mesalamine products based on bioequivalence, and, on July 21, 2017, approved a generic version of Asacol HD. D. 509 ¶¶ 318-19; D. 545 ¶¶ 318-19.

After Delzicol launched, Mylan, Teva and Zydus filed ANDAs for Delzicol with Paragraph IV certifications. D. 450 ¶ 328; D. 510 ¶ 328.

K. Other Ulcerative Colitis Treatments

There is a dispute between the parties regarding the extent to which Asacol 400mg is a product competing with other ulcerative colitis treatments. Before discussing the various facts relevant to that determination, however, it is useful to provide a brief overview of the way pharmaceutical products are purchased.

Typically, a prescription drug is prescribed by a physician to a patient, who then takes that prescription to a pharmacy to fill. D. 453-1 at 18. The pharmacy typically orders the drug wholesale from the manufacturer and resells the drug to patients. Id. When a patient purchases a drug, if the patient has insurance, the patient will generally pay a portion of the cost of the drug, called a co-pay, and the insurer will pay the remainder. Id. Some health insurers contract with a pharmacy benefit manager ("PBM") to manage the business of providing coverage for pharmaceutical products. Id. The PBM will determine the list of drugs that it will cover, known as the formulary, and determine what steps a patient must go through to receive coverage for a drug. Id. at 19. Some PBMs will establish a higher co-pay for some drugs than others; generic drugs typically have a lower co-pay than brand-name drugs. Id. Some PBMs rely on a "tiered" system, wherein the PBM requires the patient to try one drug, usually a cheaper drug, before providing coverage for another, usually more expensive drug. Id. Drug manufacturers set prices by determining the wholesale price it will charge to pharmacies, providing rebates to PBMs, and providing rebates to patients. Id. at 18.

Asacol 400mg, Asacol HD and Delzicol were not the only drugs throughout this period that were approved as ulcerative colitis treatments. D. 450 ¶ 268; D. 510 ¶ 268. Other drugs approved by the FDA for the treatment of oral ulcerative colitis were, like Asacol 400mg, Asacol HD, and Delzicol, mesalamine-containing drugs: Apriso, generic mesalamine (including a generic version of Asacol HD authorized by Warner Chilcott), Lialda, and Pentasa; others still are

treatments based on compounds that are, like mesalamine, a type of 5-aminosalicylic acid or 5-ASA: Colazal, generic balsalazide disodium, Giazo, Azulfidine, generic sulfasalazine, Azulfidine EN-tabs and generic sulfasalazine SR. D. 450 ¶ 268; D. 510 ¶ 268; D. 452 at 24. Between 2009 and 2017, the percentage of oral dosage 5-ASA drugs sold that were Asacol-branded products (Asacol 400mg, Asacol HD, or Delzicol) fell from 42.9% to 8.4%, and, by some measures, the total output fell as well. D. 450 ¶ 269; D. 510 ¶ 269; D. 509 ¶ 332; D. 545 ¶ 332. At the same time, the percentage of oral dosage 5-ASA drugs sold that were Lialda-branded products increased from 12.1% to 28.3%. D. 450 ¶ 270; D. 510 ¶ 270.

Some PBMs excluded Asacol products from their formularies while including other oral 5-ASA drugs or gave other 5-ASA drugs preferential treatment on their formularies with respect to tiers. D. 450 ¶¶ 294-301, 306, 310; D. 510 ¶¶ 294-301, 306, 310. In some cases, the PBMs explicitly drew comparisons between the pricing and effectiveness of various 5-ASA drugs in determining what drugs would be on formulary or how they would place in the tiers. Id. Certain medical literature and certain gastroenterologists identified the various oral 5-ASA drugs as "therapeutically interchangeable." D. 450 ¶¶ 313-14; D. 510 ¶¶ 313-14.

Warner Chilcott continued to earn profits on the sale of Asacol-branded products. From 2009 to 2012, Warner Chilcott's gross margins on Asacol 400mg and Asacol HD ranged from 87% to 95%, and from 2013 to 2016, Warner Chilcott's gross margins for Asacol HD were 88% to 91% and for Delzicol were 86% to 90%. D. 509 ¶¶ 334-35; D. 545 ¶¶ 334-35.

L. Plaintiffs

The named Plaintiffs in this action are the Teamsters Union 25 Health Services & Insurance Plan ("Teamsters"), the NECA-IBEW Welfare Trust Fund ("NECA-IBEW"), the Wisconsin Masons' Health Care Fund ("Masons"), and the Minnesota Laborers Health and Welfare Fund

("Laborers"). The Teamsters are headquartered in Massachusetts, and the Plaintiffs contend that the Teamsters made purchases of Asacol 400mg, Asacol HD, or Delzicol in Massachusetts, New Jersey, Missouri, and New Hampshire during the relevant time period. D. 124 ¶¶ 13-14; D. 450 ¶¶ 335-336; D. 510 ¶¶ 335-336. The NECA-IBEW are headquartered in Illinois and made purchases of Asacol 400mg, Asacol HD, or Delzicol during the relevant time period in Indiana, Missouri, Wisconsin, Alabama, Florida, Illinois, Kentucky, and Kansas. D. 124 ¶ 15; D. 450 ¶ 337; D. 510 ¶ 337. The Masons are headquartered in Wisconsin and made purchases of Asacol 400mg, Asacol HD, or Delzicol in Wisconsin during the relevant time period. D. 450 ¶ 339; D. 510 ¶ 339. The Laborers are headquartered in Minnesota and made purchases of Asacol, Asacol HD, or Delzicol in Minnesota, Ohio, Wisconsin, Iowa, and Arizona during the relevant time period. D. 450 ¶ 340; D. 510 ¶ 340.

III. Procedural History

The procedural history of this case is recounted in detail in the Court's Memorandum and Order on the motion to dismiss, D. 110. Currently pending before this Court are the parties' motions to exclude expert testimony, D. 426; D. 427; D. 428; D. 429; D. 430; D. 431; D. 444, the Plaintiffs' motion for class certification under Fed. R. Civ. P. 23(b)(3), D. 380, and the Defendants' motion for summary judgment, D. 445. The Court held a hearing regarding these pending motions on October 26, 2017. D. 556.

IV. Motions to Strike Expert Testimony

A. Standard of Review

Pursuant to Fed. R. Evid. 702, a qualified expert witness can testify "in the form of an opinion, or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." United States v. Mooney, 315 F.3d 54, 62 (1st Cir.

2002) (quoting Fed. R. Evid. 702). The district court is tasked with "ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 597 (1993). "[T]he district court must perform [this] gatekeeping function by preliminarily assessing 'whether the reasoning or methodology . . . properly can be applied to the facts in issue'" by examining multiple factors through a case-specific inquiry. Seahorse Marine Supplies, Inc. v. P.R. Sun Oil Co., 295 F.3d 68, 80-81 (1st Cir. 2002) (quoting Daubert, 509 U.S. at 592-93). "As long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co., 161 F.3d 77, 85 (1st Cir. 1998) (citations omitted). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596.

B. Motion to Exclude Testimony of Todd Clark

The Defendants move to exclude the testimony of Todd Clark ("Clark"), an expert in the pharmaceutical industry, D. 426-5 at 3-4. Clark opines that "one or more generic versions of Asacol 400mg would have entered the market at or within a short time period after the product's July 2013 patent expiration if Warner Chilcott had not executed the Asacol-to-Delzicol hard switch." D. 426-5 at 9.

The Defendants first contend that Clark's opinion is speculative because it is impermissibly based on general industry information rather than actual data about which companies filed ANDAs in preparation for launch of a generic version of Asacol 400mg. D. 426-1 at 7-8. Specifically, the Defendants contend that information concerning whether generic manufacturers were

technologically capable of producing a generic version of Asacol 400mg is "irrelevant" to the question of whether a generic manufacturer would have entered. D. 426-1 at 7.

In forming his opinion, Clark relied upon "industry norms, [his] experience, the nature of the product, the number of companies that we do know were interested, [and] the number of companies that would typically be interested in a product of this size," in a "holistic approach" rather than a quantitative simulation. D. 426-3 at 21. In drafting the report, Clark reviewed historical data regarding generic entry, D. 426-5 at 16, both generally and specifically with respect to treatments for ulcerative colitis, D. 426-5 at 17; developments in the international market for mesalamine products, D. 426-5 at 21-22; the technical capacities of generic manufacturers to produce the drug, D. 426-5 at 35; the incentives for generic manufacturers to consider entering the market, D. 426-5 at 20; the ability of generic manufacturers to obtain FDA approval, based on guidance released by the FDA on the standards for bioequivalence, D. 426-5 at 42; and public statements by generic manufacturers, D. 426-5 at 51. In Clark's experience of twenty five years in the pharmaceutical industry, D. 426-3 at 11, these are relevant factors in predicting the likelihood of generic entry. D. 426-3 at 21.

The Defendants acknowledge that the publicly available ANDA information is incomplete, because the publicly available information does not show which generic manufacturers had ANDAs with a Paragraph III certification pending at the time that Warner Chilcott pulled Asacol 400mg from the market, D. 509 ¶ 279, decreasing the incentives for a generic manufacturer to see that ANDA through to the tentative or final approval which would have been made public. Because the available information on ANDA filings is incomplete in this respect, excluding Clark's testimony because it does not focus on the ANDA filings does not seem warranted. The Defendants provide no reason to conclude that the technological capabilities of generic

manufacturers, or any other factors relied upon by Clark, are wholly irrelevant to the forecast of generic entry. The factors relied upon by Clark constitute a sufficiently reliable foundation for forecasting generic entry. Clark's choice not to rely on whatever publicly available ANDA filings existed goes to the weight, rather than the admissibility, of his testimony. See Packgen v. Berry Plastics Corp., 46 F. Supp. 3d 92, 110 (D. Me. 2014).

Second, the Defendants contend that Clark's testimony is inadmissible because Clark chose not to use a quantitative simulation to forecast generic entry. D. 426-1 at 9; D. 426-3 at 21. Even assuming a quantitative simulation might have been a superior method of forecasting generic entry, Clark's failure to do so does not render his testimony inadmissible. The standard for admissibility is not whether Clark's methodology is the best; only whether it is "methodologically reliable" and rests on "good grounds," Milward v. Acuity Specialty Prods. Corp., 639 F.3d 11, 15 (1st Cir. 2011) (citations omitted), which the Court concludes it does.

Finally, the Defendants contend that Clark may not opine on what intention the Defendants had in pulling Asacol 400mg from the market. D. 426-1 at 12. The Plaintiffs agree that Clark will not opine on the Defendants' intentions. D. 502 at 18. For all these reasons, the Court denies the motion to exclude Clark's expert opinion.

C. Motion to Exclude Testimony of Rena Conti

The Defendants move to exclude the testimony of Dr. Rena Conti ("Conti"). D. 427. The Plaintiffs have proffered Conti's opinion in predicting the effect of generic entry of Asacol 400mg on the members of the putative class if Warner Chilcott had not pulled Asacol 400mg from the market. D. 427-3 at 2. Conti is an Associate Professor of Health Economics at the University of Chicago with a Ph.D. from Harvard University in Health Policy. D. 427-3 at 3-4. She has published articles in peer-reviewed journals regarding the effect of generic entry on

pharmaceutical markets. D. 427-3 at 3-4. Conti gathered data on the pricing and sales of the Asacol-branded products and other ulcerative colitis drugs and data on the historical effect of generic entry on the prices and sales of products sold for other comparable drugs (termed "yardstick products") to model the effect on the class based on certain scenarios of generic entry provided by the Plaintiffs' counsel. D. 427-3 at 13-26.

First, the Defendants contend that Conti's model does not align with the class definition and, therefore, does not meet the standard laid out by the Supreme Court in Comcast Corp. v. Behrend, 569 U.S. 27, 35 (2013) that "any model supporting a [putative class representative's] damage case must be consistent with its liability case." D. 427-1 at 6-9. These arguments do not go to the admissibility of Conti's testimony, but rather the appropriateness of certifying the class, and are addressed below.

Next, the Defendants argue that Conti impermissibly relies on assumptions provided by the Plaintiffs' counsel regarding generic entry scenarios, D. 427-1 at 10-11; that Conti does not remove uninjured class members from her analysis and therefore exaggerates the total damages, D. 427-1 at 11-14, 18-19; that Conti impermissibly extrapolates the effect of generic entry on the market for Asacol 400mg based on other products that are not comparable to Asacol 400mg, D. 427-1 at 14-17; and that Conti failed to limit damages to the four states in which the named Plaintiffs made purchases, D. 427-1 at 17.

1. Assumptions Regarding Generic Entry

Conti's choice to rely on scenarios provided by the Plaintiffs' counsel, supported by the expert testimony from Clark and McGuire, does not provide a basis for excluding her testimony. "When facts are in dispute, experts sometimes reach different conclusions based on competing versions of the facts." Advisory Committee Notes to Rule 702 of the Federal Rules of Evidence.

As the Court will discuss below, there remains a genuine dispute of material fact regarding the possibility of generic entry. It is up to the factfinder to determine whether the assumptions relied on by Conti are accurate, and thus whether to accord any weight to her testimony. See Fontenot v. Safety Council of Sw. La., No. 2:16-cv-84, 2017 WL 3588200, at *8 (W.D. La. Aug. 16, 2017).

2. Failure to Remove Uninjured Class Members

Conti's purported failure to remove uninjured class members from her damages calculation is similarly not grounds to exclude her testimony under Rule 702. The Defendants contend that Conti's model overestimates damages in the following ways: Conti does not exclude the "substantial percentage" of third party payors that would have been uninjured because they would have paid less for the brand-name product than the generic product due to the higher co-pays charged to consumers for brand-name products and manufacturer rebates, D. 427-1 at 12-13; that Conti failed to account for brand-loyal consumers who would have stayed with Asacol 400mg even if a generic version had been available, D. 427-1 at 9; that Conti failed to exclude consumers who paid no co-pay or used coupons, D. 427-1 at 13; and that Conti failed to account for consumers who would have shifted to Asacol HD or other drugs in the but-for world, D. 427-1 at 18-19.

The Defendants' contention that there is a substantial percentage of uninjured third-party payors rests on the estimate of Dr. Bruce Strombom ("Strombom"), the Defendants' expert, on the price of generic Asacol 400mg in the but-for world. D. 427-5 at ¶ 33. That estimate is based on the application of assumptions based on actual data from the entry of a generic version of Asacol HD, which Conti contends is not an appropriate comparator because there is currently only nine months of data available on prices of generic Asacol HD, while full penetration of a generic product usually takes over a year and the market for Asacol HD was smaller and, therefore, would attract less price competition than the market for Asacol 400mg would have. D. 427-5 at 14-15.

Nevertheless, the disagreement between Conti and Strombom over which drugs constitute appropriate comparators is not grounds to exclude Conti's testimony. The but-for prices provided by the two experts are based on their different perspectives on the various characteristics of Asacol 400mg, which guided the choice of different comparator products. This dispute appears to be within "the range where experts might reasonably differ," and thus the jury should "decide among the conflicting views of experts." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 153 (1999).

Conti's assumptions about the percentage of "brand-loyal" consumers are not very different from the ones presented by the Defendants. The Defendants' expert, Strombom, estimated that approximately 5,000 consumer class members would be "brand-loyal" (i.e., would have chosen to continue purchasing Asacol HD or Delzicol even in the presence of a generic version of Asacol 400mg). D. 401-1 at 24. Strombom utilized data from benchmark products indicating that 30-40% of consumers continue to purchase the brand-name product in the first year of generic availability, dropping to 10% by the third year of generic availability. D. 401-1 at 23-24, 86. Conti, using benchmark data from other products, concluded that approximately 12.2% of class members would have purchased Asacol HD or Delzicol even in the presence of a generic version of Asacol 400mg on the market by the end of the first year of generic availability, dropping to approximately 8.6% at the end of thirty-one months of generic availability. D. 384-1 at 75; D. 384-1 at 29. Thus, between the two reports, both experts conclude that the percentage of "brand-loyal" consumers after 31 months would be between 8.6% and 10%; the experts conclude that there would be different rates of attrition over the course of that period. This dispute, again, appears to be within the range in which experts might reasonably disagree, as opposed to a way in which Conti's testimony is "so fundamentally unsupported that it can offer no assistance to the

jury." In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig., 612 F. Supp. 2d 116, 131 (D. Mass. 2009) (citation omitted).

Conti's purported failure to account for customers with no co-pay or whose co-pay was effectively reduced to zero because of a coupon is similarly not a basis to exclude her testimony. Conti estimated the percentage of consumers with zero co-pay plans and excluded them from her analysis. D. 427-3 at 28. Conti also estimated the impact of coupons provided to consumers by taking data from the Defendants' financial statements. D. 427-3 at 30. She estimated that 6% or fewer of prescriptions were affected by a coupon – and because each patient filled multiple prescriptions, fewer than 6% of patients would have had all of their purchases subject to a coupon that reduced the price to zero. D. 427-3 at 30. Neither the Defendants' briefing nor Strombom's report sufficiently explain why these adjustments are so flawed as to undermine the reliability of her proffered opinion. D. 427-1 at 13; D. 427-8 at 25-26.

Finally, the Defendants contend that Conti's testimony should be excluded because her model does not account for the percentage of consumers who are uninjured because they would have responded to an increase in the price of Asacol 400mg by switching to either Asacol HD or another ulcerative colitis drug. D. 427-1 at 18. But, as discussed below, there continues to be a genuine dispute of material fact over the elasticity of consumer demand for Asacol 400mg and other ulcerative colitis treatments. Like Conti's assumptions about generic entry, her assumptions about the substitutability of other ulcerative colitis treatments is supported by the testimony of another of the Plaintiffs' experts, and will be subject to findings by the factfinder, and thus does not constitute a reason to exclude her testimony.

3. Choice of Yardstick Product

The Defendants contend that Valcyte, the "yardstick product," or product based on which Conti made assumptions about the likely effect of generic entry, was inappropriate because, unlike Asacol 400mg, the yardstick product does not involve safety concerns associated with DBP. This argument is unpersuasive, as the Plaintiffs contend that a generic version of Asacol 400mg might also have been formulated without DBP, meaning that any opinion supporting their claims would not need to account for patient safety concerns regarding DBP.

The Defendants next contend that Valcyte is different from Asacol 400mg in that it is more expensive; it did not have the same active ingredient as any other treatment on the market; and it is not an ulcerative colitis treatment. D. 427-1 at 19. The Defendants contend that Conti should have used Asacol HD as a yardstick instead. D. 427-1 at 19. However, Conti chose Valcyte as a yardstick product because, unlike Asacol HD, Valcyte had, before generic competition, similar total sales as Asacol 400mg and Valcyte had multiple generic entrants rather than a single authorized generic entrant. D. 427-3 at 23-24. This dispute over which features of Asacol 400mg are most salient, and therefore are most important to select for in a yardstick product, are within the range of reasonable disagreement by experts, and fall short of the standard required to exclude Conti's opinion.

4. Limiting Calculation to Four States

The Defendants contend that Conti's opinion must also be excluded because her model includes damages estimates from more than the states in which the named Plaintiffs made relevant purchases. D. 427-1 at 17. As discussed below, however, the Court concludes that the Plaintiffs have standing to bring claims under the laws of states in which any class member made purchases and, therefore, rejects this basis for excluding or limiting Conti's anticipated testimony.

D. Motion to Exclude Testimony of Richard Frank

The Defendants move to exclude the testimony of Dr. Richard Frank ("Frank"). D. 428. The Plaintiffs proffer Frank as an expert in defining the relevant market of products with which Asacol 400mg competes. D. 428-3 at 2. Frank is a Professor of Health Economics at Harvard University Medical School and has been engaged in health economics for over thirty years. D. 428-3 at 4.

Frank began by surveying the market for anti-inflammatory therapeutics, including multiple treatments for ulcerative colitis and all 5-ASA drugs. D. 428-3 at 30. Relying on FDA data, among other sources, Frank charted the differences between these products in approved indications, formulation, timing, and adverse effects. D. 428-3 at 32. After excluding certain drugs, Frank analyzed the relative wholesale prices over time of the various products and concluded that "price patterns suggest no real evidence of price changes that could lead to product substitution among the branded drugs in the analysis." D. 428-3 at 39. Rather "the relative prices for these drugs were relatively constant over time," indicating that "price competition was relatively unimportant in shifting demand away from the Asacol drugs to Lialda and/or Apriso, and rather that attribute competition (differentiated product competition) was the primary driving force." D. 428-3 at 39. Frank concluded, based on a full review of the cited data, that if Warner Chilcott had raised the prices of its Asacol products by 5%, it would not have appreciably reduced sales or profits – an example of the "hypothetical monopolist" test used by the Department of Justice in evaluating the antitrust impact of horizontal mergers. D. 428-3 at 70-71. Frank then examined the gross margins earned by the Defendants for the Asacol products and concluded that the gross margins were significantly higher than the gross margins for either generic products or products facing generic competition, providing evidence of a monopoly. D. 428-3 at 75-79. Frank

concluded that "the fact that virtually all branded firms pay rebates to insurers and PBMs (especially for tier placement on formularies) does not alter a branded firm's ability to increase and sustain higher supra-competitive branded prices." D. 428-3 at 79. Finally, Frank noted that Warner Chilcott's promotional spending on Asacol HD and Delzicol accounted for over 10% of net revenues and "high levels of promotional spending imply that firms have high enough margins to provide a return to their promotional spending." D. 428-3 at 80.

As to Frank's opinion, the Defendants first argue that gross profits and promotional spending are irrelevant to the analysis of the Defendants' market power in the relevant market. D. 428-1 at 5-9. The Court disagrees; while they may not be sufficient alone to prove market power, they are certainly relevant to an analysis of market power. See Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp., 79 F.3d 182, 196 (1st Cir. 1996) (stating that "market power . . . arises when the defendant (1) can profitably set prices well above its costs" (citation omitted)). Moreover, Frank does not rely exclusively on these factors in reaching his conclusions, but combines an analysis of those factors with the pricing over time of the Defendants' product and the evidence of switching between products. D. 428-3 at 2-7.

Second, the Defendants contend that historic price increases are irrelevant and the ability of the hypothetical monopolist to exact a five percent price increase profitably has no place outside of the horizontal merger context. D. 428-1 at 9-10, 16-17. But the hypothetical monopolist test is the "touchstone of market definition," even in contexts outside of horizontal mergers. Coastal Fuels of P.R., 79 F.3d at 198.

Third, the Defendants contend that Frank inappropriately uses wholesale prices without accounting for rebates to third-party payors, leading him to ignore competition between brand-name manufacturers for formulary placement with PBMs. D. 428-1 at 12-16. While Frank did

use wholesale prices, he also concluded that it was not necessary to account for rebates because rebates were smaller than the price increases. D. 428-3 at 79. The only evidence the Defendants have offered to support their contention that Frank erred in this conclusion is the statement of an Allergan employee, indicating that PBMs that he negotiated with told him that rebates for Lialda exceeded forty or fifty percent of list price. D. 428-15 at 3. This is not sufficient to show that Frank's use of wholesale prices and rationale for doing so are an unreliable basis for his opinion.

Finally, the Defendants argue that Frank inappropriately provided a medical opinion regarding the differences between competing ulcerative colitis treatments that he was not qualified to give. D. 428-1 at 17-18. This argument is unavailing; Frank compiled and reviewed reports documenting certain characteristics of various drugs, including FDA sources, to inform his expert economic analysis, and the Defendants will be permitted to challenge the validity of the bases of his opinion at trial.

E. Motion to Exclude Testimony of Irwin Jacobs

The Defendants move to exclude the testimony of Dr. Irwin Jacobs ("Jacobs"). D. 429. The Plaintiffs first proffer Jacobs as an expert regarding the therapeutic characteristics of Asacol 400mg and Delzicol and the potential for creating a version of Asacol 400mg with DBP without using a capsule. D. 429-3 at 9. Jacobs, in formulating his opinion, relied upon documents provided by Warner Chilcott; a report submitted by the Defendants' expert on the subject, Dr. Robbins; experience with the pharmaceutical industry; documents from the FDA's communication with Warner Chilcott; and his own expertise in the field. D. 429-3 at 9-19. Jacobs concluded that "[i]t was possible to achieve safety and bioequivalence to original Asacol 400mg tablets with reformulated Asacol 400mg tablets that replaced DBP with DBS without changing the dosage form to a capsule;" that there was no need to address the problem of microfractures by means of

encapsulation; and that "[t]here is no technical or scientific reason why a company would need to encapsulate the tablet to accommodate a change to DBS formulation." D. 429-3 at 10-11.

The Plaintiffs also proffer Jacobs as an expert on the potential challenges that generic manufacturers would face in trying to create a generic version of Asacol 400mg. Jacobs concluded that "no major scientific or technological hurdles existed to prevent drug companies from developing a generic version of Asacol [400mg] that could meet [the] FDA's bioequivalence requirements and enter the market after Asacol [400mg]'s patents expired." D. 429-4 at 5. He reviewed the conclusions of the Defendants' expert, Dr. Juergen Siepmann, regarding certain purported difficulties in developing a generic version of Asacol 400mg, and concluded that none of those purported difficulties were valid or material. D. 429-4 at 5.

The Defendants next contend that Jacobs' testimony is speculative because Jacobs does not identify a particular generic manufacturer with the capability of producing a generic version of Asacol 400mg. D. 429-1 at 6. Jacobs, however, used sufficiently reliable information about the technological capabilities of generic manufacturers generally, based upon other products they produced and the specific characteristics of the Asacol 400mg product, in reaching his conclusion. The Defendants next contend that Jacobs impermissibly took account of the fact that generic manufacturers produced generic versions of two other mesalamine products – Asacol HD and Lialda – in reaching his conclusions, despite the fact that Asacol HD and Lialda are different products from Asacol 400mg. D. 429-1 at 7. But Jacobs relied on those products because they were similar to Asacol 400mg in ways that made it reasonable to draw an inference about the ease of creating a generic version of Asacol 400mg from information about Asacol HD and Lialda. D. 429-5 at 28.

The Defendants also argue that Jacobs' conclusions regarding the feasibility of formulating a version of Asacol 400mg without DBP and without a capsule are inadmissible. The Defendants first contend that Jacobs, in concluding that the FDA would have approved P&G's Asacol 400mg tablets made with DBS and without a capsule, relied only on P&Gs in vitro dissolution studies, whereas the FDA would have required more thorough testing. D. 429-1 at 11. But this contention is not at odds with Dr. Jacob's testimony. Rather, Jacobs opined that, based on his expertise, the academic literature and the experiments that were completed by P&G, "human trials had a very high likelihood of success." D. 429-3 at 20.

The Defendants additionally contend that Jacobs inappropriately discounted a December 2012 study by Warner Chilcott on microfractures because they were done in a "water environment." D. 429-1 at 12-13. In Jacobs' report, he dismissed the study because "it contains a small sample size, it is not a controlled experiment, and there is no substantiation of the conclusions." D. 429-3 at 31. Jacobs opined that because microfractures originate in the manufacturing, shipping, and handling process – which are dry settings – a water environment is not the appropriate environment in which to test for the development of microfractures, D. 429-5 at 51, even though the microfractures ultimately manifest in the water environment of the human body.

The Defendants also seek to exclude Jacobs' opinions on the Defendants' intent; the likelihood of certain action by the FDA such as approval of a product; and the relative costs of manufacturing an encapsulated versus non-encapsulated tablet. D. 429-1 at 15-16. But, the Plaintiffs agree that Jacobs will not testify about the Defendants' intent. D. 505 at 17. And, while Jacobs is not an expert in regulatory matters, he is a scientist who reviewed the technical documents released by the FDA on bioequivalence testing and opined on whether generic

manufacturers would be able to meet those technical specifications – which is, along with manufacturing costs, within his scope of expertise. D. 429-3 at 5-6.

Finally, the Defendants seek to exclude Jacobs's testimony weighing the credibility of the evidence regarding the existence of a microfracture problem or the likelihood of generic entry, because his testimony would usurp the role of the jury. D. 429-1 at 16. This is not the case where an expert is doing so in explaining his review of the scientific evidence in rendering an opinion, a function that would aid the jury pursuant to Fed. R. Evid. 702 and the jury will be instructed that they are only required to give what weight, if any, they deem they should as to any expert or lay testimony.

F. Motion to Exclude Testimony of David Kessler

The Defendants move to exclude the testimony of Dr. David Kessler ("Kessler"). D. 430. The Plaintiffs proffer Kessler, a former Commissioner of the FDA, as an expert on the FDA's policy with respect to DBP and the Asacol products. D. 430-3 at 26-32. Kessler reviewed the regulatory history of Asacol 400mg, Asacol HD, and Delzicol; the physical properties of Asacol 400mg, Asacol HD, and Delzicol; the history of interactions between the FDA and P&G and its successors about the Asacol products; and the history of FDA policy on DBP. D. 426-3 at 9-25. Based on this information, Kessler concluded that Warner Chilcott could have reformulated Asacol 400mg to remove DBP through a supplement to the Asacol NDA and that the FDA did not require Warner Chilcott to remove Asacol 400mg from the market or require Warner Chilcott to switch to a capsule formulation. D. 426-3 at 26-30.

The Defendants first argue that Kessler's deposition testimony raised new opinions not disclosed in his initial report and those additional opinions should be excluded. D. 430-1 at 6. See Fed. R. Civ. P. 26(2)(B); In re Zoloft Sertralinehydrochloride Prods. Liab. Litig., 176 F. Supp. 3d

483, 496 (E.D. Pa. 2016). Specifically, the Defendants contend that Kessler went beyond the scope of his report in opining regarding the version of Asacol 400mg sold in the United Kingdom and the swallowability of the Delzicol capsule. D. 430-1 at 6. But Kessler did opine in his report that the Defendants could have reformulated a DBP-free version of Asacol 400mg without a capsule, D. 430-3 at 32, and merely offered the U.K. formulation as additional rationale for this opinion in the deposition. Because the U.K. formulation has been discussed by other experts, there is no clear prejudice from Kessler discussing it as well, despite his failure to reference it specifically in his report. Similarly, Kessler also opined that the FDA did not require the capsule, for any safety-related reason or otherwise, D. 430-3 at 30-32, and the swallowability was an explanation in the deposition for why the capsule is not an inherently safer formulation. Compare D. 430-3 at 29-31 with D. 430-4 at 98, 126. Again, there is no prejudice to the Defendants as to this issue.

The Defendants next contend that Kessler's opinions stating that the FDA would have approved a formulation of Asacol 400mg without DBP and without a capsule are inadmissible because Kessler was not the FDA Commissioner at the time and cannot speculate about what the FDA would have done. D. 430-1 at 8-9. But, Kessler is unquestionably an expert in the process of FDA decision-making, and to the extent that the FDA's actions in a but-for world are matters for the fact-finder to determine, based upon whether it chooses to credit such opinion, the Court does not conclude that such opinion is beyond the bounds of Rule 702. See In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., No. 3:09-MD-02100-DRH, 2011 WL 6302287, at *13 (S.D. Ill. Dec. 16, 2011) (finding that "[a]s the former Commissioner of the FDA, with unquestioned knowledge of the regulatory scheme and requirements, Kessler may testify about what a reasonable FDA official would have done . . . because his experience uniquely

qualifies for him to do so"). The cases cited by the Defendants, D. 430-1 at 8-9, do not compel a contrary result.

The Defendants next seek to exclude Kessler's opinion that the FDA never required the Defendants to withdraw Asacol 400mg once Delzicol was launched, both for reasons similar to those cited above (which the Court does not accept) and because the record does not support that conclusion. D. 430-1 at 10. As to the latter point, the record does not show any evidence that the FDA did or was about to require the Defendants to pull DBP-containing Asacol 400mg from the market; rather, it shows that the FDA allowed DBP-containing Asacol HD to stay on the market for some time after Warner Chilcott pulled Asacol 400mg.

The Defendants also move to exclude Kessler's testimony regarding generic entry on the grounds that Kessler was only offered as a regulatory expert. D. 430-1 at 12-13. But the opinions of Kessler regarding generic entry are focused on the lack of regulatory barriers to generic entry, and explaining why the experiences of Par and Roxane – which had submitted ANDAs with Paragraph IV certifications and met with regulatory barriers – were not applicable to generic manufacturers that might have submitted ANDAs with Paragraph III certifications. D. 430-10 at 27. This is a fundamentally regulatory opinion and thus within the scope of Kessler's expertise.

Finally, the Defendants move to exclude Kessler's testimony on technical formulation issues; the standard of care for ulcerative colitis patients; and the intentions of the executives of the Defendants. D. 430-1 at 16-22. The Plaintiffs, however, do not seek to have Kessler opine on these topics. D. 506 at 12-15.

G. Motion to Exclude Testimony of Thomas McGuire

The Defendants move to exclude the testimony of Dr. Thomas McGuire ("McGuire"). D. 431. The Plaintiffs engaged McGuire, a Professor of Health Economics at Harvard Medical School, to opine regarding "if Warner Chilcott's withdrawal of Asacol 400mg precluded

competition and harmed consumers," and "on whether, had Asacol 400mg not been withdrawn from the market, rational, competitively acting generic firms would have been likely to enter after patent expiry." D. 431-7 at 3-4.

McGuire opines that it would be profit-maximizing for Warner Chilcott to pull Asacol 400mg from the market only if doing so would lead to higher profits for Delzicol, which would derive from consumers who preferred Asacol 400mg but were forced to switch to an alternative and chose Delzicol. D. 431-7 at 53-54. He concluded that, based on an analysis of yardstick products, generic entry for Asacol 400mg would have been likely if Warner Chilcott had not pulled Asacol 400mg from the market. D. 431-7 at 76.

The Defendants first contend that McGuire impermissibly assumed the possibility of generic entry without pointing to any particular potential entrants. D. 431-1 at 7. That argument fails for the same reason it was rejected above for Clark's testimony. Second, the Defendants contend that McGuire did not calculate the quantity of lost profits, but only calculated the lost revenue and inferred the lost profits from that. D. 431-1 at 8. But the Defendants do not explain why that inference is flawed – especially given the other evidence in the record, provided by Frank, that Asacol 400mg was a highly profitable drug. Third, the Defendants contend that McGuire impermissibly ignored the safety hazards of DBP. D. 431-1 at 9. But, as discussed above, this is not a reason to exclude his testimony.

Fourth, the Defendants challenge McGuire's model, which indicates that a hard switch by a brand-name manufacturer generally suppresses generic entry because the brand-name manufacturer would not pull a profitable product from the market unless it could make up those profits by increased sales of the new product that would come from consumers who preferred the old product and would likely have adopted a generic competitor to that product. D. 431-7 at 58.

The Defendants contend that this model has no "limiting principle" and thus would not be useful to a jury. D. 431-1 at 11. But this type of objection goes to the weight, rather than admissibility, of McGuire's testimony, and can be raised before a fact-finder in cross-examination.

Fifth, the Defendants contend that McGuire impermissibly failed to incorporate into his analysis the pro-competitive benefits of Delzicol. D. 431-1 at 11-12. However, the presence of any pro-competitive benefits of Delzicol is a disputed issue of material fact here. The Defendants are free to challenge McGuire's assumption that there were no procompetitive benefits to Delzicol before the jury, but it is not grounds for excluding his testimony.

Sixth, the Defendants argue that McGuire's test would create, in the mind of the jury, an impermissible presumption of anti-competitive conduct wherever a brand-name manufacturer executes a hard switch, which is not a proposition of law that has been adopted by any court or an economic theory published in any economic journal. D. 431-1 at 12-14. Other courts have, however, found that hard switches may be anti-competitive. See, e.g., New York ex rel. Schneiderman v. Actavis PLC (In re Namenda), 787 F.3d 638, 652 (2d Cir. 2015). McGuire's economic analysis provides an explanation for why a hard switch might generally be anticompetitive, but there is no reason for the jury to conclude that such is the case here. The fact that McGuire's theory has not yet been published is not alone grounds for its exclusion at trial. The reasons proffered by the Defendants for why not all hard switches are anticompetitive are all appropriate grounds for cross-examination.

Seventh, the Defendants seek to exclude the portion of McGuire's testimony that supports his conclusion that the introduction of Delzicol did not lead to a drop in the price of Asacol HD. D. 431-1 at 14. The Defendants contend that McGuire did not specify for them at his deposition whether he used the invoice date, accrual date or pay date to calculate the relevant date to associate

with particular price data, and thus must be excluded. D. 431-1 at 15. But, the Court does not conclude that this is a sufficient basis alone for the drastic measure of excluding this opinion and declines to do so.

Eighth, the Defendants contend that McGuire erred by using price data that did not reflect rebates given to third-party payors and did not include comparisons to relevant similar ulcerative colitis drugs. D. 431-1 at 16-17. But McGuire did adjust the price data to reflect rebates from the manufacturer, D. 431-7 at 64, and the Court does not conclude that such adjustment is insufficient. McGuire's analysis of price data was limited to the general proposition that prices for Asacol HD trended up from December 2012 to August 2013, so his failure to analyze price trends in other drugs is irrelevant – he does not purport to opine that Asacol HD prices moved in a way that was different from other drugs. D. 431-7 at 65.

Finally, the Defendants contend that McGuire's conclusions about the likelihood of generic entry should be excluded because McGuire does not identify any particular generic manufacturer that would have entered. The Court rejects this argument for McGuire as it did for Clark.

H. Motion to Exclude Testimony of Bruce Strombom

The Plaintiffs move to exclude the testimony of Dr. Bruce Strombom ("Strombom"), the Defendants' expert. D. 444. Strombom opines about the number of uninjured class members, certain putative defects in Conti's model and the aggregate damages calculation. D. 453-1 at 3-4. The Plaintiffs contend that Strombom's testimony about the number of uninjured consumers should be excluded because Strombom classifies consumers as "uninjured" where the consumer experienced an overcharge but later received recoupment for that overcharge, in contrast to legal precedent, which holds that an antitrust injury occurs "the moment the purchaser incurs an overcharge, whether or not that injury is later offset" by "savings attributable to the same or related transaction." In re Nexium Antitrust Litig., 777 F.3d 9, 27 (1st Cir. 2015). D. 453 at 2. For the

purposes of the class certification inquiry, the Court applies First Circuit law and does not rely on this portion of Strombom's analysis. For the purposes of the total damages calculation the jury must perform, however, Strombom's opinions regarding the likely impact of generic entry, the importance of rebates and coupons in offsetting damages and price trends in a but-for world remain of value, and therefore the Court does not exclude them. D. 453-1 at 4.

V. Class Certification

A. The Plaintiffs' Proposed Class

The Plaintiffs seek to certify a class defined as follows:

> All persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price for Delzicol or Asacol HD in Arizona, California, Florida, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Vermont, West Virginia, Wisconsin, and the District of Columbia for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, during the period July 31, 2013 through and until the anticompetitive effects of Defendants' unlawful conduct cease and also purchased and/or paid for some or all of the purchase price for Asacol 400mg prior to July 31, 2013.
>
> The following groups are excluded from the Class:
>
> a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;
>
> b. All persons or entities who purchased Asacol 400mg, Asacol HD, or Delzicol only directly from Defendants or for resale;
>
> c. All government entities, except for government-funded employee benefit plans;
>
> d. Fully insured health plans (i.e., plans that purchased insurance from another third party payor covering 100% of the plan's reimbursement obligations to its members);
>
> e. Pharmacy benefit managers;
>
> f. All entities whose only post-July 31, 2013 purchases of Asacol HD and Delzicol were in Massachusetts, Missouri, or Vermont;

g. "Flat co-pay" "Cadillac Plan" consumers who made purchases only via fixed dollar co-payments that do not vary between brand and generic drugs;

h. Consumers who purchased Asacol HD prior to March 8, 2013 or who purchased Asacol 400mg, Asacol HD, or Delzicol only through a Medicaid program; and

i. The judges in this case and any members of their immediate families.

D. 380 at 1-2.

B. Standing

The Defendants contend that the Plaintiffs lack standing to bring claims under the laws of any state where one of the named Plaintiffs has not allegedly made a purchase. D. 400 at 7. Article III imposes a "threshold requirement" that "those who seek to invoke the power of federal courts must allege an actual case or controversy" by pleading "some threatened or actual injury resulting from the putatively illegal action." O'Shea v. Littleton, 414 U.S. 488, 493 (1974). "[I]f none of the named plaintiffs purporting to represent a class establishes the requisite of a case or controversy with the defendants, none may seek relief on behalf of himself or any other member of the class." Id. at 494. Additionally, "a plaintiff must demonstrate standing for each claim he seeks to press." DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 352 (2006).

The Court addresses the standing question before certifying the class. See Modell v. Eliot Sav. Bank, 139 F.R.D. 17, 20 (D. Mass. 1991) (stating that "[w]hen the issue of standing is raised by a party, this Court must resolve that issue before considering the class certification requirements of Rule 23"); In re Evergreen Ultra Short Opportunities Sec. Litig., 275 F.R.D. 382, 387 (D. Mass. 2011) ("courts often decide standing at the class certification stage or earlier"); In re Eaton Vance Corp. Sec. Litig., 219 F.R.D. 38, 40-41 (D. Mass. 2003) ("[t]he burden is on the party invoking federal jurisdiction, here the named plaintiffs, to meet each of the standing requirements"). See also O'Shea, 414 U.S. at 494-95.

Article III "requires that federal courts may only adjudicate an actual 'case or controversy.'" In re Prudential Ins. Co., 148 F.3d 283, 306 (3d Cir. 1998). For Article III standing, a plaintiff must have suffered an "injury in fact" by the defendants' conduct for which the plaintiff seeks redress. Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 103 (1998). Similar to Nexium, there is no dispute that each named plaintiff allegedly paid overcharges as a result of Defendants' alleged success in suppressing generic competition to Asacol 400mg and the named plaintiffs seek monetary relief for those injuries. Nexium, 777 F.3d at 32 (noting that it is "undisputed that the named plaintiffs have shown that they were overcharged for at least one Nexium transaction during the class period, establishing standing"); see In re Relafen Antitrust Litig., 221 F.R.D. 260, 267-68 (D. Mass. 2004).

The same is shown here for the named plaintiffs' standing to bring this class action, where each named plaintiff has suffered the same injury in fact as a result of the Defendants' conduct. That is, to show standing, the named plaintiffs must assert an injury in fact – but they need not assert the same claims as the putative class members that, here, arise under the laws of different states.[2] To require more for Article III standing from the named plaintiffs is to jump forward to a Rule 23 certification analysis about whether the named plaintiffs' claims are typical and common of those of the class and whether the named plaintiffs are adequate representatives of the class. Even in the Rule 23 analysis, however, there is no requirement that putative class members share "identical claims." Piazza v. Ebsco Indus., Inc., 273 F.3d 1341, 1351 (11th Cir. 2001).[3]

[2] Because the named plaintiffs have standing to assert a claim based on the allegedly anticompetitive conduct of the Defendants, they also have standing to represent a putative class of similarly injured parties. The issue of which specific state laws govern the dispute at issue is a choice of law question, not a standing question. See In re Buspirone Litig., 185 F. Supp. 2d 363, 377. The parties appear to be in agreement that the dispute will be governed by the laws of the state in which the qualifying purchase was made.

[3] The Court is mindful of the disagreement between courts about this issue where named plaintiffs, like the named plaintiffs here, assert the same injury-in-fact but under the laws of some state laws in which they have not made a qualifying purchase. Compare Blessing v. Sirius XM Radio, Inc., 756 F. Supp. 2d 445, 452 (S.D.N.Y. 2010) with In

C. Class Certification: Burden of Proof and Standard of Review

A class action may be certified only if "(1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class." Fed R. Civ. P. 23(a). Where, as here, the Plaintiffs have moved to certify the class under Fed. R. Civ. P. 23(b)(3), the Court must also determine whether "questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed R. Civ. P. 23(b)(3). "[T]he district court must undertake a 'rigorous analysis' to determine whether plaintiffs me[e]t the four threshold requirements of Rule 23(a) (numerosity, commonality, typicality, and adequacy of representation) and Rule 23(b)(3)'s two additional prerequisites." Nexium, 777 F.3d at 17-18 (quoting Comcast, 569 U.S. at 33).

1. Numerosity Is Satisfied Here

To certify a class action, "the class [must be] so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). "'Impracticability' does not mean 'impossibility,' but only the difficulty or inconvenience of joining all members of the class." Advert. Specialty Nat'l Ass'n v. FTC, 238 F.2d 108, 119 (1st Cir. 1956). "No minimum number of plaintiffs is required . . . but generally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met." García-Rubiera v. Calderón, 570 F.3d 443, 460 (1st Cir. 2009) (quoting Stewart v. Abraham, 275 F.3d 220, 226-27 (3d Cir. 2001)); see In re Relafen Antitrust Litig., 218 F.R.D. 337, 342 (D. Mass. 2003).

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re Propranolol Antitrust Litig., 249 F. Supp. 3d 712, 727 (S.D.N.Y. 2017). But, even considering this disagreement, the Court concludes that Article III standing is satisfied here based upon the analysis above.

The Plaintiffs contend that they have met their burden of showing numerosity because the proposed class includes most individuals who filled a prescription for Asacol HD or Delzicol in the Class states, D. 381 at 14, and in 2013, there were 318,000 prescriptions for Asacol HD and 128,000 prescriptions for Delzicol in those states. D. 384-1 at 32. The Defendants respond that the number of prescriptions filled is not the same as the number of consumers who made purchases, because a single consumer may have filled multiple prescriptions. D. 400 at 12. It is true that the number of prescriptions is not the same as the number of consumers, however, it is reasonable to use "common sense assumptions" to conclude that if there were over 446,000 relevant prescriptions filled in one year, there were more than 40 individual consumers – even assuming some attrition based on class exclusions. See In re Playmobil Antitrust Litig., 35 F. Supp. 2d 231, 239 (E.D.N.Y. 1998). The Court thus finds that the Plaintiffs have met their burden of proving numerosity under Rule 23(a)(1).

2. Commonality

The Plaintiffs must also demonstrate that "there are questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). The Plaintiffs contend that the common questions of law or fact include, inter alia, the relevant market definition, the existence of monopoly power on the part of the Defendants, and the market effect of the Defendants' decision to pull Asacol 400mg off the market. The Defendants do not contest that the commonality requirement is met, but rather contend that issues common to the class do not predominate over individual issues, as is required by Rule 23(b)(3). D. 400 at 13. The Court finds that the commonality requirement is satisfied.

3. Typicality

Rule 23(a)(3) requires that the "claims or defenses of the representative parties are typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). "The representative plaintiff

satisfies the typicality requirement when its injuries arise from the same events or course of conduct as do the injuries of the class and when plaintiffs' claims and those of the class are based on the same legal theory." In re Credit Suisse–AOL Sec. Litig., 253 F.R.D. 17, 23 (D. Mass. 2008) (citation omitted). The Plaintiffs contend that the named plaintiffs' claims are typical of the class because the named plaintiffs, like all class members, overpaid for Asacol HD and Delzicol as a result of the Defendants' decision to pull Asacol 400mg from the market. D. 381 at 15.

The Defendants contend that the named plaintiffs – all unions – are not sufficiently similar to the individual consumers and health insurers included in the class. D. 400 at 13. Specifically, they contend that the Laborers and Masons were able to pass on the putative overcharge to others and so suffered no net injury, unlike other class members, and that the Laborers suffered no net injury because it received rebates that fully compensated it for the putative overcharge. Id. An antitrust injury, however, occurs "the moment the purchaser incurs an overcharge, whether or not that injury is later offset" by "savings attributable to the same or related transaction." Nexium, 777 F.3d 9 at 27. Even if the named plaintiffs did not suffer a net injury, the named plaintiffs still experienced an injury – the putative overcharge – and seek to recover on that injury on the basis of an antitrust claim, just like the other class members. The Court finds that the typicality requirement is satisfied.

4. Adequacy

Rule 23(a)(4) requires that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). "[A] class representative must be part of the class and 'possess the same interest and suffer the same injury' as the class members." Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 625–26 (1997) (quoting East Tex. Motor Freight Sys., Inc. v. Rodriguez, 431 U.S. 395, 403 (1977) (alteration in original)). A putative representative must show

"first that the interests of the representative party will not conflict with the interests of any of the class members, and second, that counsel chosen by the representative party is qualified, experienced and able to vigorously conduct the proposed litigation." Andrews v. Bechtel Power Corp., 780 F.2d 124, 130 (1st Cir. 1985). "[P]erfect symmetry of interest is not required and not every discrepancy among the interests of class members renders a putative class action untenable." Matamoros v. Starbucks Corp., 699 F.3d 129, 138 (1st Cir. 2012). "Only conflicts that are fundamental to the suit and that go to the heart of the litigation prevent a plaintiff from meeting the Rule 23(a)(4) adequacy requirement." Id. (quoting 1 William B. Rubenstein, Newberg on Class Actions § 3:58 (5th ed. 2012).

The Defendants contend that the named plaintiffs are not adequate representative parties because, unlike the other class members, the named plaintiffs are third party payors who were able to offset the alleged overcharge in the price of Asacol HD or Delzicol by recouping the overcharge from the consumer through co-pays, from the manufacturer through rebates, or from employers through contributions. D. 400 at 15. As described above, however, the antitrust injury occurs at the moment of the overcharge and the presence of offsetting transactions does not change the fact of injury. Thus, there is no reason to conclude that the presence of offsetting transactions would make the named plaintiffs inadequate representatives.

The Defendants further contend that the Plaintiffs' damages model created a "conflict" because Conti's model removed consumers who had not used Asacol 400mg prior to July 30, 2013, but did not similarly exclude third-party payors who did not purchase Asacol 400mg prior to July 30, 2013. D. 400 at 15. The Defendants argue that this feature shows that the Plaintiffs "did not ask Conti to make the same adjustment for their clients as they did for consumers," demonstrating the inadequacy of the class representatives. Id. But, as Conti explains, there is good reason for

making this exclusion for individual consumers but not for third-party payors. She opines that "[u]nlike the consumer of an Asacol HD or Delzicol prescription who may be new to using the franchise, a TPP is much more likely than not to have paid for an Asacol 400mg prescription as well . . . since they cover so many consumers and pay for many prescription drug purchases." D. 414 at 12. The Court concludes that there is no conflict created between the named plaintiffs and members of the purported class on this basis and that the Plaintiffs have met their burden as to adequacy.

5. Rule 23(b)(3) Predominance

Rule 23(b)(3) requires the Court to find that "the questions of law or fact common to class members predominate over any questions affecting only individual members." Fed. R. Civ. P. 23(b)(3). The focus of the predominance inquiry is "whether proposed classes are sufficiently cohesive to warrant adjudication by representation." Amchem, 521 U.S. at 623. When conducting a Rule 23(b)(3) analysis, the Court must determine whether there is "reason to think that [individualized] questions will overwhelm common ones and render class certification inappropriate." Halliburton Co. v. Erica P. John Fund Inc., 134 S. Ct. 2398, 2412 (2014). This requires a district court to "formulate some prediction as to how specific issues will play out in order to determine whether common or individual issues predominate in a given case." Waste Mgmt. Holdings, Inc. v. Mowbray, 208 F.3d 288, 298 (1st Cir. 2000). "To meet the predominance requirement, the party seeking certification must show that 'the fact of antitrust impact can[] be established through common proof' and that 'any resulting damages would likewise be established by sufficiently common proof.'" Nexium, 777 F.3d at 18 (quoting In re New Motor Vehicles Canadian Exp. Antitrust Litig., 522 F.3d 6, 20 (1st Cir. 2008)) (emphasis and alteration in original).

"Predominance is not defeated by individual damages questions as long as liability is still subject to common proof." In re New Motor Vehicles, 522 F.3d at 28.

a) Ascertainability

Rule 23(b)(3) carries an "implied" requirement that the class definition be sufficiently definite such that the class members are "ascertainable." See Nexium, 777 F.3d at 19; Matamoros, 699 F.3d at 139; see also In re Lidoderm Antitrust Litig., No. 14-md-02521, 2017 U.S. Dist. LEXIS 24097, at *105 (N.D. Cal. Feb. 21, 2017); Carrera v. Bayer Corp., 727 F.3d 300, 306 (3d Cir. 2013). The presence of sufficiently "objective criteria" in the class definition renders the class sufficiently ascertainable. Nexium, 777 F.3d at 19; Matamoros, 699 F.3d at 139. Where the proposed class may contain uninjured members, "[a]t the class certification stage, the court must be satisfied that, prior to judgment, it will be possible to establish a mechanism for distinguishing the injured from the uninjured class members" that is "administratively feasible" and "protective of the defendants' Seventh Amendment and due process rights." Nexium, 777 F.3d at 19.

The Defendants argue that the Plaintiffs have failed to propose a definite class in which the members of the class are ascertainable because the Plaintiffs have not proposed an administratively feasible mechanism for distinguishing injured from uninjured class members at this stage of the litigation. D. 400 at 10-11. The Plaintiffs, however, did propose such a mechanism. The Plaintiffs proposed that "[i]n a Court-approved notice, Class members will be asked to submit a claim form, along with data and documentation that may be deemed necessary for consideration. The Claims Administrator will evaluate each claim pursuant to a formula proposed by Plaintiffs and approved by the Court." D. 381-3 at 8. In Nexium, the First Circuit held that where a class contained uninjured members, a claims administration process where class members were required to submit affidavits or other individual evidence to show that they were injured would be sufficiently feasible

and protective of the defendants' Seventh Amendment and due process rights. Nexium, 777 F.3d at 19-21.

b) Damages Methodology

Rule 23(b)(3) also places a burden on the putative class to present a damages model that establishes "that damages are capable of measurement on a classwide basis." Behrand, 569 U.S. at 34. This model must be "consistent with its liability case, particularly with respect to the alleged anticompetitive effect of the violation," id. at 35 (quoting ABA Section of Antitrust Law, Proving Antitrust Damages: Legal and Economic Issues 57, 62 (2d ed. 2010)). "In other words, the defendants cannot be held liable for damages beyond the injury they caused." Nexium, 777 F.3d at 18. Even if there are some disparities, "the need for some individualized determinations at the liability and damages stage does not defeat class certification." Id. at 21.

The Plaintiffs contend that Conti's model matches the liability theory they have presented – specifically, that the Defendants exercised monopoly power over the relevant market by pulling Asacol 400mg from the market and thereby preventing generic competition. D. 381 at 24. Conti's model estimates the damages to end-payors by simulating what the price and quantity sold of Asacol 400mg would have been if the Defendants had not pulled Asacol 400mg from the market, under several potential scenarios of generic entry, based on historical data from other products regarding the effect of generic entry on the price and quantity sold of the brand-name product. D. 384-1 at 21-24. Conti concludes that, under each of these scenarios of generic entry, end-payors would have paid less for Asacol 400mg than they paid for Asacol HD and Delzicol. D. 384-1 at 32-33.

The Defendants argue that Conti's model does not match the liability theory presented by the Plaintiffs because Conti's model relied upon prescription-level data rather than patient-level

data. D. 400 at 16. Because of this flaw, they contend, Conti's model is unable to calculate the damages based on the class definition used by the Plaintiffs: a class definition that requires that a member both purchased Asacol 400mg before July 31, 2013 and purchased Delzicol or Asacol HD after July 31, 2013, and did not purchase Asacol HD before March 8, 2013. D. 400 at 17. Conti did adjust her calculations to approximate the effect of excluding patients who did not take Asacol 400mg prior to July 31, 2013, based on the fraction of prescriptions for Asacol HD and Delzicol that were new. D. 384-1 at 31. The Defendants contend that Conti's model does not similarly adjust for patients who purchased Asacol HD prior to March 8, 2013 (when Asacol 400mg was still on the market). D. 400 at 17. But the Defendants present no reason to conclude that there is a sizable population of patients who consumed Asacol 400mg prior to July 31, 2013, and consumed Asacol HD prior to March 8, 2013 such that it would create the necessary divergence between the Plaintiffs' class definition and damages model. That is, "[c]alculations need not be exact," so long as the model is "consistent with its liability case." Comcast, 569 U.S. at 35 (citation omitted).

The Defendants also contend that Conti's model diverges from the class definition by failing to exclude third-party payors who did not purchase Asacol 400mg prior to July 31, 2013. D. 400 at 17. But, as the Plaintiffs point out, a third-party payor makes purchases on behalf of many patients, and Conti assessed that only a de minimus number of third-party payors had no purchases whatsoever of Asacol 400mg, so no adjustment was needed to ensure conformity with the dual-purchase aspect of the class definition for third-party payors. D. 411 at 10.

The Defendants next contend that Conti's model fails to match the liability theory by inappropriately assuming that, but for the purportedly unlawful conduct, the number of Asacol HD consumers would stay static from February 2013 forward without any further switching from Asacol 400mg to Asacol HD. D. 400 at 18. This argument, however, amounts to an argument

that the model's assumptions are flawed, which the Defendants will have an opportunity to argue before a factfinder.

The Defendants further contend that Conti's model does not appropriately exclude third-party payors from the states for which the third-party claims have been dismissed. D. 400 at 18. Conti has explained, however, that she did in fact exclude third-party claims from those states using data on aggregate expenditures by state to estimate the relative proportion of sales from those states, D. 384-1 at 31, even as Defendants' expert, Strombom contests that such was an appropriate adjustment.

Finally, the Defendants contend that Conti's model does not correspond to the liability theory because it does not account for the role of PBMs, who may reimburse third-party payors for drug expenses that exceed contractually agreed-to limits. D. 400 at 19. But the fact that PBMs may have reimbursed third-party payors for some portion of the antitrust injury does not mean that Conti's model should have included an adjustment for PBMs. Rather, because "antitrust injury occurs the moment the purchaser incurs an overcharge," Nexium, 777 F.3d at 27, the subsequent reimbursement by PBMs does not have any bearing on the Plaintiffs' liability theory.

c) Common Proof of Antitrust Impact

"To meet the predominance requirement, the party seeking certification must show that 'the fact of antitrust impact can[ ] be established through common proof'" Id. at 18 (quoting New Motor Vehicles, 522 F.3d at 20) (alternation in original). The Plaintiffs allege that the injury they suffered came in the form of the excessively high prices they paid for Asacol HD and Delzicol, as a result of the Defendants' decision to pull Asacol 400mg from the market. D. 381 at 22. They contend that Conti's model establishes that a single model can provide common proof of antitrust impact. D. 381 at 23.

The Defendants contend that Conti's model cannot provide common proof of antitrust impact for several reasons. They first argue that Conti's model is unable to estimate damages for injured and uninjured members of the class separately. D. 400 at 19. But, at the class certification stage, it is not necessary to separate out injured and injured members; it is only necessary to establish that "prior to judgment, it will be possible to establish a mechanism for distinguishing the injured from the uninjured class members." Id. at 19. As discussed above, it will be possible to establish such a mechanism.

The Defendants next contend that Conti's model inappropriately assumes that the effect of generic entry into the market for Asacol 400mg would mirror historical patterns of other drugs; that Conti's model inappropriately assumes that generic entry would occur; and that Conti's model does not adequately account for the fact that generic versions of Asacol 400mg would still contain DBP. D. 400 at 20-21. None of these arguments, however, challenge the Plaintiffs' contention that Conti's model provides a common proof of antitrust impact. These challenges to the assumptions underlying Conti's model are susceptible to class-wide contestation and the Defendants will have the opportunity to make these challenges before the factfinder.

Finally, the Defendants contend that individual issues predominate with respect to antitrust impact because Conti's model includes many uninjured members. D. 400 at 22. The Defendants identify the following as uninjured class members: consumers with no co-pay; brand-loyal consumers who would have switched to Asacol HD or Delzicol even in the presence of generic Asacol 400mg; consumers who would have paid the same co-pay for brand-name and generic products; third-party payors that are fully insured; consumers who used coupons; third-party payors who received manufacturer rebates; third-party payors who had a risk-sharing arrangement with a PBM or employer; and third-party payors who were able to recoup higher costs by passing

them on to employers. D. 400 at 22-24. As described above, several of these groups suffered the antitrust injury of higher prices, and are, therefore, not uninjured (even if they were subsequently reimbursed), such as third-party payors who received manufacturer rebates, third-party payors who had a risk-sharing arrangement with a PBM or employer, third-party payors who are fully insured and third-party payors who were able to recoup higher costs by passing them on to employers. Some of these groups are explicitly excluded from the class, such as, for example, consumers with flat co-pays. Thus, even if Conti has not explicitly excluded those prescriptions from her model, the damages attributable to those consumers all accrue to the third-party payor – who is included in Conti's model. As for consumers who used coupons, Conti's model adjusted for the aggregate impact of those consumers, and the Defendants make no specific criticism of the way in which Conti's model adjusted for them. D. 384-1 at 30.

As for brand-loyal consumers, as the First Circuit explained in Nexium, "the need for some individualized determinations at the liability and damages stage does not defeat class certification," at least so long as there is only a *de minimis* number of uninjured class members. Nexium, 777 F.3d at 21. The question is whether there is a *de minimis* number of brand-loyal consumers or not. As discussed above, between the two expert reports, it seems that, by the end of the relevant period, somewhere around 10% of the class members would have opted for Asacol HD or Delzicol even in the presence of generic Asacol 400mg. But, even so, the Defendants do not sufficiently show that even 10% of the class constitutes more than a *de minimis* number sufficient to deny class certification.

6. Rule 23(b)(3) Superiority

A putative class seeking certification under Rule 23(b)(3) also bears the burden of showing that a class action "is superior to other available methods for fairly and efficiently adjudicating the

controversy," Fed. R .Civ. P. 23(b)(3). Nexium, 777 F.3d at 18. The Court considers four factors within the superiority inquiry:

> (A) the class members' interests in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already begun by or against class members; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (D) the likely difficulties in managing a class action.

Fed. R. Civ. P. 23(b)(3). The Court here considers the alternatives to a class action, conscious that "[t]he policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for an individual to bring a solo action prosecuting his or her rights." Amchem, 521 U.S. at 617 (quoting Mace v. Van Ru Credit Corp., 109 F.3d 338, 344 (1997)) (internal quotation marks omitted). The superiority inquiry thus ensures that litigation by class action will "achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results." Id. (quoting Advisory Committee's Notes on Fed. R. Civ. P. 23).

The Plaintiffs contend that a class action is superior to other methods of adjudication because each individual plaintiff's damages are relatively small and thus would not have sufficient incentive to bring individual lawsuits. D. 381 at 25. They further contend that the case is sufficiently administrable as a class action. D. 381 at 26-27. The Defendants contend that the class is not administrable because, as they argued with respect to ascertainability, the Plaintiffs have not proposed a mechanism to separate uninjured from injured class members. D. 400 at 25. But, for the same reasons this Court rejected that argument in the ascertainability context, it rejects that argument here.

VI. Summary Judgment

The Defendants move for summary judgment on several grounds. D. 449. First, they contend that the hard switch from Asacol 400mg to Delzicol was not exclusionary; second, they contend that the state-law antitrust claims are precluded by federal food and drug law; third, they contend that the Plaintiffs cannot prove antitrust standing because there would not have been any generic entry even without the hard switch; fourth, they contend that they did not exercise any monopoly power; and fifth, they contend that Delzicol had procompetitive benefits which outweighed any anticompetitive effects of the hard-switch. D. 449 at 3-4.

A. Standard of Review

The Court will grant summary judgment when there is no genuine dispute on any material fact and the undisputed facts show that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). "An issue is genuine if 'it may reasonably be resolved in favor of either party' at trial, and material if it 'possess[es] the capacity to sway the outcome of the litigation under the applicable law.'" Iverson v. City of Boston, 452 F.3d 94, 98 (1st Cir. 2006) (alteration in original) (internal citations omitted). The movant "bears the burden of demonstrating the absence of a genuine issue of material fact." Rosciti v. Ins. Co. of Pa., 659 F.3d 92, 96 (1st Cir. 2011) (quoting Carmona v. Toledo, 215 F.3d 124, 132 (1st Cir. 2000)). If the moving party meets this burden, then the non-movant must "with respect to each issue on which she would bear the burden of proof at trial, demonstrate that a trier of fact could reasonably resolve that issue in her favor." Borges ex rel. S.M.B.W. v. Serrano-Isern, 605 F.3d 1, 5 (1st Cir. 2010). "The test is whether, as to each essential element, there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party." DeNovellis v. Shalala, 124 F.3d 298, 306 (1st Cir. 1997) (internal quotation mark and citation omitted). In deciding a summary judgment motion,

the Court views the record in the light most favorable to the non-moving party, drawing all reasonable inferences in his favor. Noonan v. Staples, Inc., 556 F.3d 20, 25 (1st Cir. 2009).

Under the state-law antitrust claims brought by the Plaintiffs, which the parties agreed are construed in parallel with the federal Sherman Act, the Plaintiffs must prove "(1) that the defendant possesses 'monopoly power in the relevant market,' and (2) that the defendant has acquired or maintained that power by improper means." Town of Concord, Mass. v. Bos. Edison Co., 915 F.2d 17, 21 (1st Cir. 1990). "[I]mproper methods of acquiring or maintaining monopoly power" are also referred to as "exclusionary conduct," which is "conduct, other than competition on the merits or restraints reasonably 'necessary' to competition on the merits, that reasonably appears capable of making a significant contribution to creating or maintaining monopoly power." Id. (citation omitted). To show that conduct is exclusionary, the Plaintiff must show that the conduct has an "anticompetitive effect," that is "it must harm the competitive process and thereby harm consumers. In contrast, harm to one or more competitors will not suffice." United States v. Microsoft Corp., 253 F.3d 34, 58 (D.C. Cir. 2001) (emphasis in original). If the Plaintiff has successfully demonstrated anticompetitive effect, the Defendant has the burden of showing a pro-competitive justification, that is, that "its conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal." Id. at 59. If the Defendant does so, "then the burden shifts back to the plaintiff to rebut that claim." Id. Finally, the Plaintiffs must show that, as private parties, they have standing to bring the antitrust action, which involves showing, among other things, that they were harmed by the Defendants' exclusionary conduct.

B. Preemption by Federal Law

The Defendants contend that, regardless of the merits of the Plaintiffs' antitrust claims, the Defendants are entitled to summary judgment on the ground that the Plaintiffs' state law causes of action are preempted by federal food and drug law. Specifically, they contend that it was "impossible" for them to comply both with the FDA's mandate to stop selling of Asacol 400mg with DBP and with the putative state law requirement that they continue selling Asacol 400mg with DBP. D. 449 at 23.

This argument fails for two reasons. First, the record does not show that the FDA prohibited the Defendants from selling Asacol 400mg with DBP. As discussed above, the FDA provided a series of recommendations to the Defendants that they stop selling products with DBP, but at no point did the FDA require the Defendants to stop selling Asacol 400mg with DBP. Rather, the record shows that the Defendants continued to sell a different product with DBP, Asacol HD, until 2016, and even then there was no indication that the FDA was about to prohibit the Defendants from selling the product.

Second, the Plaintiffs do not contend that state antitrust law required the Defendants to continue selling Asacol 400mg with DBP; rather, they contend that the Defendants could have reformulated Asacol 400mg with DBS rather than DBP without switching to a new product under a new NDA, which would have preserved the likelihood of generic entry. D. 508 at 20. There's no suggestion that this course of action would have been prohibited by the FDA. In fact, the record shows that the Defendants pursued exactly this course of action for Asacol HD. D. 509 ¶ 125.

C. Monopoly Power in the Relevant Market

The Defendants contend that there is no genuine dispute of material fact regarding the Plaintiffs' contention that the Defendants wielded monopoly power in the relevant market.

"Market power can be shown through two types of proof," either through "direct evidence of market power," such as "actual supracompetitive prices and restricted output," or "circumstantial evidence of market power." Coastal Fuels of P.R., 79 F.3d at 196–97.

1. Direct Evidence

The Plaintiffs first contend that they have shown direct evidence of monopoly power by pointing to the high gross margins of Asacol 400mg as proof of supracompetitive prices. D. 508 at 41. The Defendants contend that the Plaintiffs' showing of high gross margins is not direct evidence of monopoly power because such margins are standard for brand-name manufacturers of a patented product and those manufacturers cannot be considered *per se* monopolists. D. 449 at 45. In support of this proposition, they cite to In re Remeron Direct Purchaser Antitrust Litig., 367 F. Supp. 2d 675, 683 (D.N.J. 2005). In that case, the court concluded that the plaintiffs' evidence that the brand-name manufacturer maintained significantly higher prices prior to generic entry insufficient to create a genuine dispute of material fact regarding direct evidence of market power. Id. It reasoned that the plaintiffs provided "no evidence of excessive price-cost margins or restricted output," and that the brand-name manufacturer had incurred "initial fixed costs," such as "research, development, and the cost of being the first to gain FDA drug approval." Id. at 682. The court concluded that "[i]f the direct evidence approach can ever supplant the market definition approach in a § 2 context, it can only do so where a reasonable juror could find the evidence conclusive as to why Defendants' prices were higher." Id. at 683. Essentially, the court recited two propositions in reaching its conclusion: first, that determining whether a price is supracompetitive requires taking cost into account; and second, that both variable and fixed costs should be taken into account. Only the first was necessary to its decision, because the plaintiffs had not even presented evidence of marginal cost.

In contrast, the court in In re Nexium, 968 F. Supp. 2d 367, 389 (D. Mass. 2013), aff'd 842 F.3d 34 (1st Cir. 2016), ruled that the plaintiffs had established direct evidence of market power by demonstrating that the prices charged were "well in excess of marginal costs," and thus explicitly did not consider the fixed costs involved.

The Court finds the approach taken in Remeron to be more applicable for products with relatively high fixed costs compared to variable costs. In the market for a product with high fixed costs, evidence that prices routinely exceed marginal costs may not necessarily be evidence that prices are supracompetitive, because even competitive prices may exceed marginal cost. See United States v. Eastman Kodak Co., 63 F.3d 95, 109 (2d Cir. 1995) (holding that "[c]ertain deviations between marginal cost and price, such as those resulting from high fixed costs, are not evidence of market power"). However, there does not appear to be evidence in the record establishing what the fixed costs for creating Asacol 400mg were and whether those costs were sufficient to justify the prices charged for Asacol 400mg. Thus, there remains a genuine dispute of material fact as to whether the prices charged for Asacol 400mg are supracompetitive, because it is at least permissible for the jury to draw an inference from the supracompetitive nature of the prices charged from the gross margin, even if evidence about the fixed costs involved in creating Asacol 400mg would undermine the strength of such inference.

The Plaintiffs also contend that they have provided direct evidence of market power based on restricted output, in the form of a total decrease in sales of oral mesalamine products after the Defendants pulled Asacol 400mg from the market. D. 508 at 42. The Plaintiffs interpret the Defendants' charts as showing that total volume of oral mesalamine prescriptions dropped around the time that Asacol 400mg was pulled from the market. D. 509 at 73. The Defendants dispute

this interpretation. D. 449 at 45. This dispute in interpretation is one that should be reserved for the factfinder.

2. Circumstantial Evidence

Circumstantial evidence of market power requires a "showing that the defendant has a dominant share in a well-defined relevant market and that there are significant barriers to entry in that market and that existing competitors lack the capacity to increase their output in the short run." Coastal Fuels of P.R. v. Caribbean Petroleum Corp., 79 F.3d at 197. "The definition of the relevant market is ordinarily a question of fact, and the plaintiff bears the burden of adducing enough evidence to permit a reasonable factfinder to define the relevant market." Flovac, Inc. v. Airvac, Inc., 817 F.3d 849, 853 (1st Cir. 2016). "The market is established by examining both the substitutes that a consumer might employ and 'the extent to which consumers will change their consumption of one product in response to a price change in another, i.e., the cross-elasticity of demand.'" Id. at 854 (quoting Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 469 (1992)).

The Plaintiffs contend that the "relevant market" to consider is the market for Asacol 400mg and the products that the FDA rated as AB-rated bioequivalents to Asacol 400mg. D. 508 at 44. The Defendants contend that the relevant market is the market of all oral 5-ASA treatments. D. 449 at 37. In support of this contention, the Defendants point to the fact that there were multiple FDA approved treatments for ulcerative colitis that the FDA, insurers, PBM, and gastroenterologists considered therapeutically interchangeable with Asacol 400mg and its bioequivalents; that the marketing documents from the Defendants and other manufacturers show that the Defendants considered Asacol 400mg to compete with other 5-ASA products; and that

Asacol 400mg lost volume just as Lialda, a competing 5-ASA drug, gained volume. D. 449 at 39-42.

The Defendants, relying upon various documents and statements, also argue that patients would switch among 5-ASA drugs, sometimes based on formulary status, which were based on the level of rebates that the manufacturer provided to the PBM. D. 449 at 43; D. 450 ¶ 239; D. 458-6 at 213; D. 458-6 at 215; D. 458-7 at 303-305. The Defendants further contend that other courts, when faced with similar facts, have concluded that the relevant market includes multiple products – not just one product and its bioequivalents. They cite first to Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 12-cv-3824, 2015 WL 1736957 (E.D. Pa. Apr. 16, 2015). In that case, the district court cited to evidence that dermatologists (the relevant specialty) considered the product at issue, Doryx, interchangeable with other products; that managed care organizations have sought to "constrain patients to substitute Doryx with other, less costly tetracyclines to treat acne," that "internal marketing documents" from the defendants also confirm that the defendant subjectively perceived Doryx as in competition with other products; and that the defendants "produced evidence of cross-elasticity of demand between Doryx and other oral tetracyclines," by way of showing that sales of Doryx fluctuated in response to the generosity of Doryx's coupon program. Id. at *9-10. They next cite to United States v. CIBA GEIGY Corp., 508 F. Supp. 1118, 1154-55 (D.N.J. 1976), in which the court determined that a particular pharmaceutical product was in the same market as other products because it was "reasonably interchangeable" with them and the testimony of the various manufacturers that they considered themselves to be in competition with one another. Finally, the Defendants cite to Bayer Schering Pharma AG v. Sandoz, Inc., 813 F. Supp. 2d 569, 576-78 (S.D.N.Y. 2011), in which the court found that a pharmaceutical product

was not a single-product market if there were combinations of other therapies that would achieve the same therapeutic effect.

The Plaintiffs contend that the key inquiry in market definition is whether, from the "perspective of consumers," the products were interchangeable such that there was significant cross-elasticity of demand, such that an increase in the price of one product in the market would lead to meaningful substitution to another product in the market. See Flovac, 817 F.3d at 855. And, they contend, consumers did not behave as if different 5-ASA drugs were interchangeable. In particular, Frank noted that internal Warner Chilcott documents indicated that the market for ulcerative colitis drugs is relatively static, with only 3% of prescriptions in a given month representing a shift from one ulcerative colitis drug to a different one. D. 428-3 at 22. Experts testified that both patient and physicians had a strong tendency to stick with a given product if it was working for the patient. D. 509 ¶¶ 347-348. According to the testimony of a Warner Chilcott employee, the rebates offered by Warner Chilcott were, in some cases, significantly less generous than the rebates offered by other manufacturers of 5-ASA products, D. 458 at 506, yet Warner Chilcott was able to persist without lowering prices to match, because patients continue to purchase Asacol 400mg. Additionally, Frank concluded that, if Warner Chilcott had raised the prices of its Asacol products by 5%, it would not have appreciably reduced sales, showing a relatively low cross-elasticity of demand between Asacol 400mg and other 5-ASA products. D. 428-3 at 70-71. While Frank's data did not account for the differential rebates provided by different manufacturers because he deemed the rebates to be sufficiently similar between manufacturers, the Court explained above that this goes to the weight rather than admissibility of his testimony.

Additionally, the Plaintiffs cite to In re Nexium, 968 F. Supp. 2d at 388, in which the court found that the plaintiffs had created a genuine dispute of material fact regarding a market definition

consisting of a single product and its generic equivalents. Id. (collecting cases also finding such a market). The court reasoned that "the reasonable interchangeability of brand Nexium with other drugs [is] a factually intensive determination better left for resolution by a jury." Id.

In Coastal Fuels of P.R., 79 F.3d at 198, the First Circuit explained that the "touchstone of market definition is whether a hypothetical monopolist could raise prices," citing the Ninth Circuit's decision in Rebel Oil Co., Inc. v. Atl. Richfield Co., 51 F.3d 1421, 1434 (9th Cir. 1995). The Ninth Circuit has explained that one way of measurement of this touchstone is whether "a monopolist in the proposed market could profitably impose a small but significant and nontransitory price increase [SSNIP]." Theme Promotions, Inc. v. News Am. Mktg. FSI, 546 F.3d 991, 1002 (9th Cir. 2008). While this SSNIP test is used most often in the merger context, see, e.g., Saint Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys., Ltd., 778 F.3d 775, 784 (9th Cir. 2015), courts have also used it outside that context. See, e.g., Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc., 588 F.3d 908, 918 (6th Cir. 2009); Theme Promotions, 546 F.3d at 1002; Golden Boy Promotions LLC v. Haymon, No. 15-cv-3378, 2017 WL 460736, at *11 (C.D. Cal. Jan. 26, 2017; IGT v. All. Gaming Corp., No. 2:04-CV-1676-RCJ-RJJ, 2008 WL 7071468, at *10 (D. Nev. Oct. 21, 2008). "Typically, the increase that is posted is five percent." In re Se. Milk Antitrust Litig., 739 F.3d 262, 277 (6th Cir. 2014).

There is a genuine dispute of fact regarding the Plaintiffs' putative market definition of a market that consisted of Asacol 400mg and its bioequivalent products. As the court found in Nexium, this fact-intensive inquiry is best left for the jury.

D. Exclusionary Conduct

1. Anticompetitive Effects

The Defendants argue that there is no genuine dispute of material fact regarding the exclusionary nature of the Defendants' decision to pull Asacol 400mg from the market when it launched Delzicol, for several reasons. D. 449 at 14. They contend first that the FDA requested the removal of products containing DBP and second that Delzicol is a safer product than Asacol 400mg. D. 449 at 14-19.

It is undisputed that the FDA requested the removal of products containing DBP and that the FDA considered the removal of DBP to have accompanying safety benefits. The question of whether the safety risk of DBP was substantive enough to justify the Defendants' conduct goes to whether the Defendants' conduct had sufficient procompetitive justification to outweigh the anticompetitive effects. Additionally, the Plaintiffs contend that the Defendants could have captured the safety benefits of removing DBP without switching to the capsule formulation that deterred generic entry.

The Defendants respond that antitrust law does not impose upon them a "duty to reformulate in a manner that will aid potential competitors." D. 449 at 20. But the Plaintiffs do not argue that the Defendants had the obligation to reformulate in the manner that would best facilitate generic entry. Rather, according to the Plaintiffs' narrative, the Defendants had already reformulated Asacol 400mg to have a DBS coating instead of a DBP coating, and instead of seeking FDA approval for that product, they needlessly included in the Asacol 400mg reformulation a patented capsule that conferred no additional value. Thus, the "duty" that Plaintiffs seek to impose on the Defendants is to refrain from reformulating in such a way that adds features – like the capsule – that have minimal or no value beyond their anticompetitive effects.

The Plaintiffs' theory is in line with the Second Circuit's decision in In re Namenda, 787 F.3d at 652. In that decision, the Second Circuit found a likelihood of success on the merits where the plaintiffs alleged a similar hard switch between brand-name products. Id. at 647-48. It reasoned that "neither product withdrawal nor product improvement alone is anticompetitive. But . . . when a monopolist combines product withdrawal with some other conduct, the overall effect is which to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive." Id. at 653-54. It concluded that "antitrust law requires [defendants] to allow generic competitors a fair opportunity to compete using state substitution laws." Id. at 658 (citation omitted).

Like the plaintiffs in Namenda, the Plaintiffs' redesign theory here would require the Defendants to engage in some conduct that they did not engage in: in Namenda, the conduct was continuing to sell the prior version of Namenda, whereas here, the conduct would be selling a version of Asacol 400mg with DBS instead of DBP, but no capsule. It is certainly relevant that the Defendants did not, at any point, sell Asacol 400mg with DBS instead of DBP with no capsule in the United States. But they did sell Asacol 400mg with DBS instead of DBP in the United Kingdom and had planned to do so in the United States for some period of time before deciding to switch to the capsule formulation.

2. Procompetitive Justification

The Defendants next contend that, even if their challenged conduct was anticompetitive, the anticompetitive effects had a procompetitive justification. Specifically, they argue that DBP-free Delzicol is safer than the DBP-containing Asacol 400mg; that Delzicol improved dissolution stability and reduced the occurrence of "early openers;" and that Delzicol served as a bridge to the novel, pediatric friendly 4 x 100mg Delzicol, which offers a lower-dose option. D. 449 at 50.

The first argument fails because, as discussed above, the Plaintiffs contend that the Defendants could have produced a DBP-free version of Asacol 400mg without switching to a capsule formulation, meaning that any safety benefits from removing DBP would have been captured as well in the Plaintiff's but-for scenario. The second argument fails because there is a genuine dispute of material fact regarding whether Delzicol improved the dissolution stability and reduced the occurrence of early openers. The record shows that the Defendants did not have any validated experimental evidence of a benefit to either dissolution stability or early openers until October 2012 – after the Defendants submitted the NDA for Delzicol to the FDA. D. 509 ¶¶ 209-213; D. 450 ¶ 163; D. 510 ¶ 163. Additionally, the Plaintiffs dispute the quality of the October 2012 studies showing a stability benefit to the capsule formulation. D. 450 ¶ 163; D. 510 ¶ 163. The third argument fails because the Defendants have presented no evidence that the Defendants needed to produce a 1x400mg formulation in order to produce the later 4x100mg formulation. Instead, the record shows that the Defendants started down the path of producing a 4x100mg capsule formulation, but temporarily shifted away from that path to focus on a 1x400mg capsule formulation that might be ready before the patents for Asacol 400mg expired.

E. Causation and Antitrust Standing

The Defendants contend that there is no genuine dispute of material fact regarding the issue of antitrust standing. "The Supreme Court has set forth a six-factor test to determine whether a plaintiff has standing to bring an antitrust action. These factors are: (1) the causal connection between the alleged antitrust violation and harm to the plaintiff; (2) an improper motive; (3) the nature of the plaintiff's alleged injury and whether the injury was of a type that Congress sought to redress with the antitrust laws ("antitrust injury"); (4) the directness with which the alleged market restraint caused the asserted injury; (5) the speculative nature of the damages; and (6) the

risk of duplicative recovery or complex apportionment of damages." RSA Media, Inc. v. AK Media Grp., Inc., 260 F.3d 10, 14 (1st Cir. 2001). "Although we technically balance the six factors to determine if standing is appropriate, this Court has emphasized the causation requirements of that test." Id.

The Defendants contend that the Plaintiffs have not shown antitrust causation, that is, they have not shown that the Defendants' purportedly anticompetitive conduct caused the Plaintiffs harm because they contend that the Plaintiffs have not shown that there would have been generic versions of Asacol 400mg produced if not for the Defendants' choice to pull Asacol 400mg from the market. D. 449 at 25. The Defendants argue that the Plaintiffs have the burden of showing that a generic manufacturer was "ready, willing, and able" to enter the Asacol 400mg market during the relevant time period. D. 449 at 25; Indium Corp. of Am. v. Semi-Alloys, Inc., 781 F.2d 879, 882 (Fed. Cir. 1985). The Defendants' argument is based on the undisputed fact that Zydus, Lupin, Roxane, and Par all did not have ANDAs pending at the time Asacol 400mg was pulled from the market, and that the Plaintiffs did not produce evidence that any other generic manufacturer had an ANDA with a Paragraph III certification pending at the time Asacol 400mg was pulled from the market. D. 449 at 28-31. The Defendants contend that the expert testimony of Clark and McGuire are too speculative because both experts fail to identify the specific generic manufacturer that would have entered but for the purportedly anticompetitive conduct. D. 449 at 31-33.

Antitrust law, however, does not support the Defendants' contention that the Plaintiffs' causation theory is too speculative if it does not identify a specific entrant that had a pending ANDA. In Microsoft, 253 F.3d at 54, the court stated that "[n]othing in § 2 of the Sherman Act limits its prohibition to actions taken against threats that are already well-developed enough to

serve as present substitutes." It held that, where the exclusionary conduct is aimed at "producers of nascent competitive technologies," the issue is "whether [competitors] reasonably constituted nascent threats at the time [the defendant] engaged in the anticompetitive conduct at issue," even if those competitors were "unproven." Id. at 79. Moreover, in antitrust suits, "juries are allowed to act on probable and inferential as well as (upon) direct and positive proof." Bigelow v. RKO Radio Pictures, 327 U.S. 251, 264 (1946). Additionally, even if the Defendants were able to prove that no ANDAs with a Paragraph III certification were pending at the time that the Defendants pulled Asacol 400mg from the market, it is undisputed that the FDA had both the authority and interest to fast-track ANDAs for Asacol 400mg, so an ANDA with a Paragraph III certification submitted after July 31, 2013 might have been approved during the relevant period. D. 509 ¶ 317.

The Defendants next contend that the FDA's bioequivalence standards prevented generic manufacturers from producing a generic version of Asacol 400mg. D. 449 at 34. But, the record reflects that the Defendants perceived the FDA's shift from requiring clinical studies to focusing on PK testing as lowering the bar for generic entry, D. 509 ¶ 289 and that another generic manufacturer, Zydus, produced generic versions of both Asacol HD and another oral mesalamine product that were approved by the FDA as bioequivalent in 2017; D. 509 at 318-320.

There is a genuine dispute of material fact as to the issue of causation. Drawing all disputed facts in favor of the Plaintiffs, as this Court must in evaluating the Defendants' motion for summary judgment, the record shows that, according to the Defendants' own documents, the industry had identified Asacol 400mg as likely to face generic entry; D. 509 ¶ 241, that generic manufacturers had significant incentives to be the first-mover to create a generic version of Asacol 400mg; D. 426-5 at 20; that generic manufacturers had the technological capability to develop a generic versions of oral delayed release mesalamine products, D. 509 ¶ 296; and historical

experience in the pharmaceutical industry indicates that it was highly likely that a generic version of Asacol 400mg would emerge. D. 509 ¶ 284. Drawing all inferences in favor of the Plaintiffs as the non-movants, there is a genuine dispute of fact over whether a generic manufacturer would have produced a generic version of Asacol 400mg within the relevant timeframe.

VII. Conclusion

For the foregoing reasons, the Court DENIES the parties' motions to exclude testimony, D. 426; D. 427; D. 428; D. 429; D. 430; D. 431; D. 444, provides the reasons for ALLOWING the Plaintiffs' motion for class certification under Fed. R. Civ. P. 23(b)(3) in D. 559, D. 380, and DENIES the Defendants' motion for summary judgment, D. 445.

So Ordered.

/s/ Denise J. Casper
United States District Judge